Intergovernmental Data Quality Task Force

Uniform Federal Policy for Quality Assurance Project Plans

Draft
Version 2
June 2001

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ACRONYMS

AA - Atomic Absorption
BOD - Biochemical Oxygen Demand
CA - Corrective Action
CAA - Clean Air Act
CERCLA - Comprehensive Environmental Response, Compensation, and Liability Act of 1980
CLP - Contract Laboratory Program
COC - Contaminants of Concern
CRDL - Contract-Required Detection Limit
CWA - Clean Water Act
DOT - Department of Transportation
DQA - Data Quality Assessment
DQIs - Data Quality Indicators
DQOs - Data Quality Objectives
EMMC - Environmental Monitoring Management Council
EPA - Environmental Protection Agency
ERA - Environmental Risk Assessment
FID - Flame Ionization Detector
FIFRA - Federal Insecticide, Fungicide, and Rodenticide Act
FS - Feasibility Study
GC - Gas Chromatograph
GC/MS - Gas Chromatography/Mass Spectrometry
GPC - Gel Permeation Chromatography
IATA - International Air Transport Association
ICP - Inductively Coupled Plasma
IPA - Initial Precision and Accuracy
IS - Internal Standard
LCS - Laboratory Control Sample
LFB - Laboratory Fortified Blank
LIMS - Laboratory Information Management Systems
LQAP - Laboratory Quality Assurance Plan
MCLs - Maximum Contaminant Levels
MDLs - Method Detection Limits
MPC - Measurement Performance Criteria
MS/MSD - Matrix Spike/Matrix Spike Duplicate
MSR - Management Systems Review
NEIC - National Enforcement Investigations Center
NIST - National Institute of Standards and Technology
NPDES - National Pollutant Discharge Elimination System
PARCC - Precision, Accuracy, Representativeness, Completeness, and Comparability
PCBs - Polychlorinated Biphenyls
PE - Performance Evaluation
PESs - Performance Evaluation Samples

ACRONYMS (Continued)

PID - Photo Ionization Detector
PQLs - Practical Quantitation Limits
PQOs - Project Quality Objectives
pre-RI - pre-Remedial Investigation
PRP - Potentially Responsible Party
QA - Quality Assurance
QA/QC - Quality Assurance/Quality Control
QC - Quality Control
QAPP - Quality Assurance Project Plan, synonymous with QAPjP
QLs - Quantitation Limits
QMP - Quality Management Plan
RA - Remedial Action
RCRA - Resource Conservation and Recovery Act
RD - Remedial Design
RI - Remedial Investigation
RIC - Reconstructed Ion Chromatogram
RLs - Reporting Limits
RPD - Relative Percent Difference
RSD - Relative Standard Deviation
RT - Retention Time
SAP - Sampling and Analysis Plan
SA/SI - Site Assessment/Site Investigation
SD - Standard Deviation
SDG - Sample Delivery Group
SDWA - Safe Drinking Water Act
SOP - Standard Operating Procedure
SQLs - Sample Quantitation Limits
SRM - Standard Reference Material
TCLP - Toxicity Characteristic Leaching Procedure
TIC - Tentatively Identified Compound
TSA - Technical Systems Audit
TSCA - Toxic Substances Control Act
VOA - Volatile Organic Analysis
XRF - X-Ray Fluorescence Spectrometry

GLOSSARY OF QUALITY ASSURANCE AND RELATED TERMS[1]

The following glossary is from EPA QA/G-5, except where noted otherwise. The IDQTF is requesting comments on terms and on the adequacy and appropriateness of the definitions.

Acceptance criteria — Specified limits placed on characteristics of an item, process, or service defined in requirements documents. (American Society for Quality Control)

Accuracy — The degree of agreement between an observed value and an accepted reference value. Accuracy includes a combination of random error (precision) and systematic error (bias) components that are due to sampling and analytical operations; a data quality indicator. (U.S. EPA Quality Assurance Management Staff (QAMS), Glossary of Quality Assurance Terms, 8/31/92 and 12/6/95)

Activity — An all-inclusive term describing a specific set of operations or related tasks to be performed, either serially or in parallel (e.g., research and development, field sampling, analytical operations, equipment fabrication), that, in total, result in a product or service.

Assessment — The evaluation process used to measure the performance or effectiveness of a system and its elements. As used here, assessment is an all-inclusive term used to denote any of the following: audit, performance evaluation (PE), management systems review (MSR), peer review, inspection, or surveillance.

Audit (quality) — A systematic and independent examination to determine whether quality activities and related results comply with planned arrangements and whether these arrangements are implemented effectively and are suitable to achieve objectives.

Bias — The systematic or persistent distortion of a measurement process, which causes errors in one direction (i.e., the expected sample measurement is different from the sample's true value).

Blank — A sample subjected to the usual analytical or measurement process to establish a zero baseline or background value. Sometimes used to adjust or correct routine analytical results. A sample that is intended to contain none of the analytes of interest. A blank is used to detect contamination during sample handling preparation and/or analysis.

Calibration — A comparison of a measurement standard, instrument, or item with a standard or instrument of higher accuracy to detect and quantify inaccuracies and to report or eliminate those inaccuracies by adjustments.

Certification — The process of testing and evaluation against specifications designed to document, verify, and recognize the competence of a person, organization, or other entity to perform a function or service, usually for a specified time.

Chain of custody — An unbroken trail of accountability that ensures the physical security of samples, data, and records.

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[1] Unless otherwise noted, this glossary's definitions were taken from EPA Guidance for Quality Assurance Project Plans, EPA/600/R-98/018, February 1998 (EPA QA/G-5).

Characteristic — Any property or attribute of a datum, item, process, or service that is distinct, describable, and/or measurable.

Comparability — A measure of the confidence with which one data set or method can be compared to another.

Completeness — A measure of the amount of valid data obtained from a measurement system compared to the amount that was expected to be obtained under correct, normal conditions.

Configuration — The functional, physical, and procedural characteristics of an item, experiment, or document.

Conformance — An affirmative indication or judgment that a product or service has met the requirements of the relevant specification, contract, or regulation; also, the state of meeting the requirements.

Contractor — Any organization or individual contracting to furnish services or items or to perform work.

Corrective action — Any measures taken to rectify conditions adverse to quality and, where possible, to preclude their recurrence.

Data Quality Assessment (DQA) — The scientific and statistical evaluation of data to determine if data obtained from environmental operations are of the right type, quality, and quantity to support their intended use. The five steps of the DQA process include (1) reviewing the DQOs and sampling design, (2) conducting a preliminary data review, (3) selecting the statistical test, (4) verifying the assumptions of the statistical test, and (5) drawing conclusions from the data.

Data Quality Indicators (DQIs) — The quantitative statistics and qualitative descriptors that are used to interpret the degree of acceptability or utility of data to the user. The principal data quality indicators are bias, precision, accuracy (bias is preferred), comparability, completeness, representativeness.

Data Quality Objectives (DQOs) — The qualitative and quantitative statements derived from the DQO process that clarify a study's technical and quality objectives, define the appropriate type of data, and specify tolerable levels of potential decision errors that will be used as the basis for establishing the quality and quantity of data needed to support decisions.

Data Quality Objectives (DQO) Process — A systematic strategic planning tool based on the scientific method that identifies and defines the type, quality, and quantity of data needed to satisfy a specified use. DQOs are the qualitative and quantitative outputs from the DQO process.

Data reduction — The process of transforming the number of data items by arithmetic or statistical calculations, standard curves, and concentration factors, and collating them into a more useful form. Data reduction is irreversible and generally results in a reduced data set and an associated loss of detail.

Data usability — The process of ensuring or determining whether the quality of the data produced meets the intended use of the data.

Design — The specifications, drawings, design criteria, and performance requirements. Also, the result of deliberate planning, analysis, mathematical manipulations, and design processes.

Detection Limit (DL) — A measure of the capability of an analytical method to distinguish samples that do not contain a specific analyte from samples that contain low concentrations of the analyte; the lowest concentration or amount of the target analyte that can be determined to be different from zero by a single measurement at a stated level of probability. DLs are analyte- and matrix-specific and may be laboratory-dependent.

Distribution — (1) The appointment of an environmental contaminant at a point over time, over an area, or within a volume; (2) a probability function (density function, mass function, or distribution function) used to describe a set of observations (statistical sample) or a population from which the observations are generated.

Document control — The policies and procedures used by an organization to ensure that its documents and their revisions are proposed, reviewed, approved for release, inventoried, distributed, archived, stored, and retrieved in accordance with the organization's requirements.

Duplicate samples — Two samples taken from and representative of the same population and carried through all steps of the sampling and analytical procedures in an identical manner. Duplicate samples are used to assess variance of the total method, including sampling and analysis.

Environmental conditions — The description of a physical medium (e.g., air, water, soil, sediment) or a biological system expressed in terms of its physical, chemical, radiological, or biological characteristics.

Environmental data — Any parameters or pieces of information collected or produced from measurements, analyses, or models of environmental processes, conditions, and effects of pollutants on human health and the ecology, including results from laboratory analyses or from experimental systems representing such processes and conditions.

Environmental data operations — Any work performed to obtain, use, or report information pertaining to environmental processes and conditions.

Environmental monitoring — The process of measuring or collecting environmental data.

Environmental processes — Any manufactured or natural processes that produce discharges to, or that impact, the ambient environment.

Environmental programs — An all-inclusive term pertaining to any work or activities involving the environment, including but not limited to characterization of environmental processes and conditions; environmental monitoring; environmental research and development; the design, construction, and operation of environmental technologies; and laboratory operations on environmental samples.

Environmental technology — An all-inclusive term used to describe pollution control devices and systems, waste treatment processes and storage facilities, and site remediation technologies and their components that may be utilized to remove pollutants or contaminants from, or to prevent them from entering, the environment. Examples include wet scrubbers (air), soil washing (soil), granulated

activated carbon unit (water), and filtration (air, water). Usually, this term applies to hardware-based systems; however, it can also apply to methods or techniques used for pollution prevention, pollutant reduction, or containment of contamination to prevent further movement of the contaminants, such as capping, solidification or vitrification, and biological treatment.

Estimate — A characteristic from the sample from which inferences on parameters can be made.

Field blank — A blank used to provide information about contaminants that may be introduced during sample collection, storage, and transport. A clean sample, carried to the sampling site, exposed to sampling conditions, returned to the laboratory, and treated as an environmental sample.

Field (matrix) spike — A sample prepared at the sampling point (i.e., in the field) by adding a known mass of the target analyte to a specified amount of the sample. Field matrix spikes are used, for example, to determine the effect of the sample preservation, shipment, storage, and preparation on analyte recovery efficiency (the analytical bias).

Finding — An assessment conclusion that identifies a condition having a significant effect on an item or activity. An assessment finding may be positive or negative, and is normally accompanied by specific examples of the observed condition.

Graded approach — The objective process of establishing the project requirements and level of effort according to the intended use of the results and the degree of confidence needed in the quality of the results. (IDQTF QAPP Manual Subgroup Consensus Definition)

Guidance — A suggested practice that is not mandatory, intended as an aid or example in complying with a standard or requirement.

Guideline — A suggested practice that is not mandatory in programs intended to comply with a standard.

Hazardous waste — Any waste material that satisfies the definition of hazardous waste given in 40 CFR 261, "Identification and Listing of Hazardous Waste."

Holding time — The period of time a sample may be stored prior to its required analysis. While exceeding the holding time does not necessarily negate the veracity of analytical results, it causes the qualifying or "flagging" of any data not meeting all of the specified acceptance criteria.

Inspection — The examination or measurement of an item or activity to verify conformance to specific requirements.

Internal standard — A standard added to a test portion of a sample in a known amount and carried through the entire determination procedure as a reference for calibrating and controlling the precision and bias of the applied analytical method.

Management — Those individuals directly responsible and accountable for planning, implementing, and assessing work.

Management system — A structured, nontechnical system describing the policies, objectives, principles, organizational authority, responsibilities, accountability, and implementation plan of an organization for conducting work and producing items and services.

Matrix spike (MS) — A sample prepared by adding a known concentration of a target analyte to an aliquot of a specific homogenized environmental sample for which an independent estimate of the target analyte concentration is available. The matrix spike is accompanied by an independent analysis of the unspiked aliquot of the environmental sample. For organics, the matrix spike is run in conjunction with a matrix spike duplicate. Spiked samples are used to determine the effect of the matrix on a method's recovery efficiency. (EPA QA/G-5 definition modified by the IDQTF Matrix Subgroup)

Mean (arithmetic) — The sum of all the values of a set of measurements divided by the number of values in the set; a measure of central tendency.

Method — A body of procedures and techniques for performing an activity (e.g., sampling, chemical analysis, quantification), systematically presented in the order in which they are to be executed.

Method blank — A blank prepared to represent the sample matrix as closely as possible and analyzed exactly like the calibration standards, samples, and quality control (QC) samples. Results of method blanks provide an estimate of the within-batch variability of the blank response and an indication of bias introduced by the analytical procedure.

Must — When used in a sentence, a term denoting a requirement that has to be met.

Nonconformance — A deficiency in a characteristic, documentation, or procedure that renders the quality of an item or activity unacceptable or indeterminate; nonfulfillment of a specified requirement.

Objective evidence — Any documented statement of fact, other information, or record, either quantitative or qualitative, pertaining to the quality of an item or activity, based on observations, measurements, or tests that can be verified.

Observation — An assessment conclusion that identifies a condition (either positive or negative) that does not represent a significant impact on an item or activity. An observation may identify a condition that has not yet caused a degradation of quality.

Organization — A company, corporation, firm, enterprise, or institution, or part thereof, whether incorporated or not, public or private, that has its own functions and administration.

Outlier — An extreme observation that is shown to have a low probability of belonging to a specified data population.

Parameter — A quantity, usually unknown, such as a mean or a standard deviation characterizing a population. Commonly misused for "variable," "characteristic," or "property."

Performance evaluation (PE) — A type of audit in which the quantitative data generated in a measurement system are obtained independently and compared with routinely obtained data to evaluate the proficiency of an analyst or laboratory.

Pollution prevention — An organized, comprehensive effort to systematically reduce or eliminate pollutants or contaminants prior to their generation or their release or discharge into the environment.

Precision — The degree to which a set of observations or measurements of the same property, obtained under similar conditions, conform to themselves; a data quality indicator. Precision is usually expressed as standard deviation, variance or range, in either absolute or relative terms. (National Environmental Laboratory Accreditation Conference (NELAC), July 1998 Standards)

Procedure — A specified way to perform an activity.

Process — A set of interrelated resources and activities that transforms inputs into outputs. Examples of processes include analysis, design, data collection, operation, fabrication, and calculation.

Project — An organized set of activities within a program.

Qualified data — Any data that have been modified or adjusted as part of statistical or mathematical evaluation, data validation, or data verification operations.

Quality — The totality of features and characteristics of a product or service that bears on its ability to meet the stated or implied needs and expectations of the user.

Quality assurance (QA) — An integrated system of management activities involving planning, implementation, assessment, reporting, and quality improvement to ensure that a process, item, or service is of the type and quality needed and expected by the client.

Quality Assurance Program Description/Plan — See *Quality Management Plan*.

Quality Assurance Project Plan (QAPP) — A formal document describing in comprehensive detail the necessary quality assurance (QA), quality control (QC), and other technical activities that must be implemented to ensure that the results of the work performed will satisfy the stated performance criteria. The QAPP components are divided into four classes: (1) Project Management, (2) Measurement/Data Acquisition, (3) Assessment/Oversight, and (4) Data Validation and Usability.

Quality control (QC) — The overall system of technical activities that measures the attributes and performance of a process, item, or service against defined standards to verify that they meet the stated requirements established by the customer; operational techniques and activities that are used to fulfill requirements for quality. The system of activities and checks used to ensure that measurement systems are maintained within prescribed limits, providing protection against "out of control" conditions and ensuring the results are of acceptable quality.

Quality control (QC) sample — An uncontaminated sample matrix spiked with known amounts of analytes from a source independent of the calibration standards. Generally used to establish intralaboratory or analyst-specific precision and bias or to assess the performance of all or a portion of the measurement system.

Quality management — That aspect of the overall management system of the organization that determines and implements the quality policy. Quality management includes strategic planning, allocation of resources, and other systematic activities (e.g., planning, implementation, and assessment) pertaining to the quality system.

Quality Management Plan (QMP) — A formal document that describes the quality system in terms of the organization's structure, the functional responsibilities of management and staff, the lines of authority, and the required interfaces for those planning, implementing, and assessing all activities conducted.

Quality system — A structured and documented management system describing the policies, objectives, principles, organizational authority, responsibilities, accountability, and implementation plan of an organization for ensuring quality in its work processes, products (items), and services. The quality system provides the framework for planning, implementing, and assessing work performed by the organization and for carrying out required quality assurance (QA) and quality control (QC).

Quantitation limit — The minimum concentration of an analyte or category of analytes in a specific matrix that can be identified and quantified above the method detection limit and within specified limits of precision and bias during routine analytical operating conditions.

Record (quality) — A document that furnishes objective evidence of the quality of items or activities and that has been verified and authenticated as technically complete and correct. Records may include photographs, drawings, magnetic tape, and other data recording media.

Recovery — The act of determining whether the methodology measures all of the analyte contained in a sample.

Remediation — The process of reducing the concentration of a contaminant (or contaminants) in air, water, or soil media to a level that poses an acceptable risk to human health.

Reporting limit — The lowest concentration or amount of the target analyte required to be reported from a data collection project. Reporting limits are generally greater than detection limits and are usually not associated with a probability level.

Representativeness — A measure of the degree to which data accurately and precisely represent a characteristic of a population, a parameter variation at a sampling point, a process condition, or an environmental condition.

Reproducibility — The precision, usually expressed as variance, that measures the variability among the results of measurements of the same sample at different laboratories.

Requirement — A formal statement of a need and the expected manner in which it is to be met.

Research (applied) — A process, the objective of which is to gain the knowledge or understanding necessary for determining the means by which a recognized and specific need may be met.

Research (basic) — A process, the objective of which is to gain fuller knowledge or understanding of the fundamental aspects of phenomena and of observable facts without specific applications toward processes or products in mind.

Scientific method — The principles and processes regarded as necessary for scientific investigation, including rules for concept or hypothesis formulation, conduct of experiments, and validation of hypotheses by analysis of observations.

Self-assessment — The assessments of work conducted by individuals, groups, or organizations directly responsible for overseeing and/or performing the work.

Sensitivity — The capability of a method or instrument to discriminate between measurement responses representing different levels of a variable of interest.

Service — The result generated by activities at the interface between the supplier and the customer, and the supplier internal activities to meet customer needs. Such activities in environmental programs include design, inspection, laboratory and/or field analysis, repair, and installation.

Shall — A term denoting a requirement that is mandatory whenever the criterion for conformance with the specification permits no deviation. This term does not prohibit the use of alternative approaches or methods for implementing the specification so long as the requirement is fulfilled.

Specification — A document stating requirements and referring to or including drawings or other relevant documents. Specifications should indicate the means and criteria for determining conformance.

Spike — A substance that is added to an environmental sample to increase the concentration of target analytes by known amounts; used to assess measurement accuracy (spike recovery). Spike duplicates are used to assess measurement precision.

Split samples (field) — Two or more representative portions taken from one sample in the field and analyzed by different laboratories. Prior to splitting, a sample is homogenized to correct for sample inhomogeneity that would adversely impact sample data comparability. Split samples are quality control samples that are used to assess sample handling procedures from field to laboratory and to evaluate interlaboratory comparability and precision. (EPA QA/G-5 definition modified by the IDQTF QA Matrix Subgroup)

Split samples (laboratory) — Two or more representative portions taken from the same sample and analyzed by different laboratories to estimate the interlaboratory precision or variability and the data comparability. (EPA QA/G-5 definition modified by the IDQTF QA Matrix Subgroup)

Standard deviation — A measure of the dispersion or imprecision of a sample or population distribution that is expressed as the positive square root of the variance and has the same unit of measurement as the mean.

Standard Operating Procedure (SOP) — A written document that details the method for an operation, analysis, or action with thoroughly prescribed techniques and steps and that is officially approved as the method for performing certain routine or repetitive tasks.

Supplier — Any individual or organization furnishing items or services or performing work according to a procurement document or a financial assistance agreement. An all-inclusive term used in place of any of the following: vendor, seller, contractor, subcontractor, fabricator, or consultant.

Surrogate spike or analyte — A pure substance with properties that mimic the analyte of interest (organics only). Surrogates are brominated, fluorinated, or isotopically labeled compounds unlikely to be found in environmental samples. They are added to samples to evaluate analytical efficiency

by measuring recovery. (EPA QA/G-5 definition modified by the IDQTF QA Matrix Subgroup; and Contract Laboratory Program (CLP))

Technical Systems Audit (TSA) — A thorough, systematic, on-site qualitative audit of facilities, equipment, personnel, training, procedures, record keeping, data validation, data management, and reporting aspects of a system.

Traceability — The ability to trace the history, application, or location of an entity by means of recorded identifications. In a calibration sense, traceability relates measuring equipment to national or international standards, primary standards, basic physical constants or properties, or reference materials. In a data collection sense, it relates calculations and data generated throughout the project back to the requirements for the quality of the project.

Trip blank — A clean sample of a matrix that is taken to the sampling site and transported to the laboratory for analysis without having been exposed to sampling procedures.

Validation — Confirmation by examination and provision of objective evidence that the particular requirements for a specific intended use have been fulfilled. In design and development, validation concerns the process of examining a product or result to determine conformance to user needs.

Variance (statistical) — A measure or dispersion of a sample or population distribution.

Verification — Confirmation by examination and provision of objective evidence that specified requirements have been fulfilled. In design and development, verification concerns the process of examining a result of a given activity to determine conformance to the stated requirements for that activity.

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EXECUTIVE SUMMARY

Introduction

The draft ***Uniform Federal Policy for Quality Assurance Project Plans*** (the UFP-QAPP Manual), prepared by the Intergovernmental Data Quality Task Force (IDQTF), provides instructions for preparing Quality Assurance Project Plans (QAPPs).[2] It is the companion document to the IDQTF's *Uniform Federal Policy for Implementing Environmental Quality Systems*. It provides project-specific instructions based on ANSI/ASQC E4 Part B. This document was developed as a joint initiative between the U.S. Environmental Protection Agency (EPA), the Department of Defense (DoD), and the Department of Energy (DOE). The purpose of the UFP-QAPP Manual is to serve as a single national consensus document that consistently and systematically implements the project-specific requirements of ANSI/ASQC E4 (***Specifications and Guidelines for Quality Systems for Environmental Data Collection and Environmental Technology Programs, Part B***) across the Federal agencies involved in the IDQTF (currently EPA, DoD, and DOE).

The UFP-QAPP Manual requires that a Quality Assurance Project Plan (QAPP) be approved for all environmental data collection projects. A QAPP will integrate technical and quality control aspects of a project throughout its life cycle, including planning, implementation, assessment, and corrective actions. The QAPP presents the steps that will be taken to ensure that environmental data collected are of the correct type and quality required for a specific decision or use. It presents an organized and systematic description of the ways in which quality assurance (QA) and quality control (QC) will be applied to the collection and use of environmental data.

Background

Many Federal agencies have independently created their own QAPP guidance. EPA has one QAPP requirements document and one guidance document that encompass all the elements of a systematic planning process that should be addressed in a QAPP. These documents are QA/R5, *EPA Requirements for Quality Assurance Project Plans* (requirements), and QA/G5, *EPA Guidance for Quality Assurance Project Plans* (guidance). DoD and DOE have independently developed their own approach to QAPP guidance and different programs or components of these agencies may also have their own approaches to developing QAPPs. In addition, although EPA has Agency-wide QAPP guidance, many EPA Regions have independently developed their own implementation tools, including supplemental QAPP guidance or "model QAPPs," with one Region's tools differing from those of another Region.

These multiple guidance documents within the different agencies do not necessarily address all of the same elements and often result in uncertainty as to what is expected, conflict between agencies, and rework. Different reviewers and preparers of QAPPs have different expectations of what should

[2]This draft guidance is based on a QAPP Compendium and UFP-QAPP Manual developed by EPA Region 1. It has been modified by a subgroup of the IDQTF to reflect comments from EPA, DoD and DOE on the Region 1 guidance, to remove Region 1 specific guidance, and to address the requirements identified by the members of the IDQTF.

be in a QAPP. An approach to a QAPP that is deemed suitable for one Region may not be suitable in another Region. A DoD component may create a QAPP that has some, but not all, of the parts EPA considers important.

Because approaches to and requirements for QAPPs differ among Federal agencies, the IDQTF believes it is necessary to implement QAPP requirements that are applicable to any Federal agency that adopts the UFP-QAPP Manual. The draft UFP-QAPP Manual, developed by the IDQTF to provide a common organizational framework and approach to QAPPs, will reduce conflict and provide all who are involved at Federal facilities with a common set of guidelines and expectations.

Scope

This document provides requirements and guidelines to Federal agencies for developing Quality Assurance Project Plans for management of environmental data collection and use and environmental technology programs. It becomes the policy for an agency when formally adopted by that agency. Each agency will determine how best to implement the policy.

The Uniform Federal Policy for Implementing Environmental Quality Systems was developed to consistently implement the quality system requirements of ANSI/ASC E-4. Similarly this draft UFP-QAPP Manual has been developed to consistently implement the project-specific requirements of that standard.

This document represents a voluntary consensus policy. Implementation is, therefore, not subject to oversight by another Federal agency or to a Notice of Violation if one agency fails to implement all or part of the policy.

Overview of Guidance

The draft ***UFP-QAPP Manual*** is comprehensive, covers a variety of topics that are sometimes found in other documents (e.g., sampling and analysis plans, work plans), and encompasses EPA's Systematic Planning Process. Several principles are important to understanding the UFP-QAPP Manual:

- The UFP-QAPP Manual is designed for use in support of any environmental program for which field data will be collected and analyzed.

- Since the content and level of detail required for individual QAPPs will vary according to the work being performed, project planners are encouraged to use a "graded approach" when preparing QAPPs. In other words, the degree of documentation, level of effort, and level of detail will vary based on the complexity of the project.

- The UFP-QAPP Manual recommends the use of tables and charts (called worksheets) to document the elements of the QAPP. The specific elements of the various tables and charts are outlined in the UFP-QAPP Manual and an accompanying QAPP workbook.

- The UFP-QAPP Manual is designed to be used with either generic QAPPs or project-specific QAPPs. When elements required by the UFP-QAPP Manual are present in other documents (e.g., SOPs), careful cross-referencing of these other documents can be used in lieu of repeating information.

- Existing QAPPs do not have to be rewritten when a Federal agency adopts the UFP-QAPP Manual. The requirements of the UFP-QAPP Manual will be applicable to QAPP revisions, as appropriate, and to new QAPPs.

Related IDQTF Documents and Products

Two documents are currently available for use with this document:

- QAPP Workbook – This contains example blank worksheets for all elements for which worksheets are recommended.

- Example QAPP – This is an example QAPP that is based on this Guidance. It uses the worksheets recommended in this policy to demonstrate how they may be completed to write a QAPP.

In addition, computer software is being developed to assist in QAPP preparation. The QAPP software will be designed as a stand-alone program, based on the QAPP requirements outlined in this document, that will prompt QAPP preparers in the compilation of required project-specific information and in the use of QAPP worksheets. When the UFP-QAPP Manual is finalized, the stand-alone program will be available to walk users through the process of developing their own QAPP.

Organization of This Document

This document is organized into five major chapters. The Introductory chapter (Chapter 1) describes the nature of this policy and provides more detail on the overall approach. Each of the subsequent four chapters address one of the four major element groups of the QAPP: Project Management and Objectives, Measurement/Data Acquisition, Assessment and Oversight, and Data Validation and Usability.

Comment is sought from all reviewers on specific issues and on the overall usefulness of this document. In a number of cases, text boxes identify areas where the IDQTF is specifically concerned with obtaining reviewer input. The issues identified by these text boxes include:

- Whether the worksheets should be optional or mandatory.
- The glossary definitions.

- The approach to data review, including data validation and verification. (The current text is taken from the Region 1 guidance on which this Uniform Federal Guidance is based. The IDQTF anticipates that this text will change, and is soliciting comments from reviewers on the nature of these changes.)

1.0 INTRODUCTION

The complexity of environmental data collection operations demands that a systematic process and structure for quality be established if decision-makers are to have the necessary confidence in the quality of data that support their decisions. This process and structure must include the means to determine whether the data are fully usable and what to do if they are not. This process and structure are provided by the Quality System used by the organization conducting the environmental data operations.

Lead organizations (see 1.2) must develop, operate, and document Quality Systems to ensure that environmental data collected or compiled for environmental programs are scientifically sound, of known and documented quality, and suitable for their intended use.

The Quality Assurance Project Plan (QAPP) integrates all technical and quality aspects for the life cycle of the project, including planning, implementation, and assessment. The purpose of the QAPP is to document planning results for environmental data operations and to provide a project-specific "blueprint" for obtaining the type and quality of environmental data needed for a specific decision or use. The QAPP documents how quality assurance (QA) and quality control (QC) are applied to an environmental data collection operation to ensure that the results obtained are of the type and quality needed and expected.

The ultimate success of an environmental program or project depends on the quality of the environmental data collected and used in decision-making, and this may depend significantly on the adequacy of the QAPP and its effective implementation. This planning must include the "stakeholders" (i.e., the data users, data producers, decision-makers, etc.) to ensure that all needs are defined adequately and that the planning for quality addresses those needs. While time spent on such planning may initially seem unproductive and costly, the penalty for ineffective planning is increased cost and lost time due to conflicts and extensive reworking.

1.1 Scope

This document provides requirements and guidelines to Federal agencies for developing Quality Assurance Project Plans for management of environmental data collection and use and environmental technology programs. It becomes the policy for an agency when formally adopted by that agency; each agency will determine how best to implement the policy.

The Uniform Federal Policy for Implementing Environmental Quality Systems was developed to consistently implement the quality system requirement of ANSI/ASC E-4, and similarly this Uniform Federal Policy for Quality Assurance Project Plans (UFP-QAPP Manual) has been development to consistently implement the project-specific requirements of that standard.

This document represents a voluntary consensus policy. Implementation is, therefore, not subject to oversight by another Federal agency or to a Notice of Violation if one agency fails to implement all or part of the policy.

1.2 Purpose

This ***Draft UFP-QAPP Manual*** is intended to provide instructions regarding the preparation of QAPPs in accordance with *Specifications and Guidelines for Quality Systems for Environmental Data Collection and Environmental Technology Programs*, ANSI/ASQC E4 (Final, January 1995). This UFP-QAPP Manual must be used by Lead Organizations and their contractors when performing environmental data collection operations. Lead organizations may include, but are not limited to, the following:

- U.S. Environmental Protection Agency Regions or offices.
- Other Federal Government agencies.
- States, Tribes, and local governments under financial agreements, including grants and cooperative agreements.
- Nonprofit organizations (e.g., volunteer organizations, interstate associations) under financial agreements, including institutions of higher education and hospitals.
- Regulated entities/facilities (e.g., potentially responsible parties) under voluntary or enforcement consent decrees, agreements, and orders.

The scope of this UFP-QAPP Manual covers all environmental data collection efforts conducted at or on Federal facilities for EPA.

The QAPP serves several purposes:

- As a *technical planning document*, it provides an overview of the project by identifying the purpose of the project; defining the project quality objectives; and outlining the field, analytical, and quality assurance/quality control (QA/QC) activities that will be used to support environmental decisions.
- As an *organizational document*, it identifies key project personnel, thereby facilitating communication.
- As an *oversight document*, it must be reviewed and approved by EPA or the delegated approval authority prior to sample collection.

The QAPP serves as a demonstration of an organization's ability to plan, implement, assess, and document project activities and should provide sufficient, detailed information to verify that these activities will result in usable data. All QAPPs must, at a minimum, include all specified information and enclosures as detailed in this UFP-QAPP Manual.

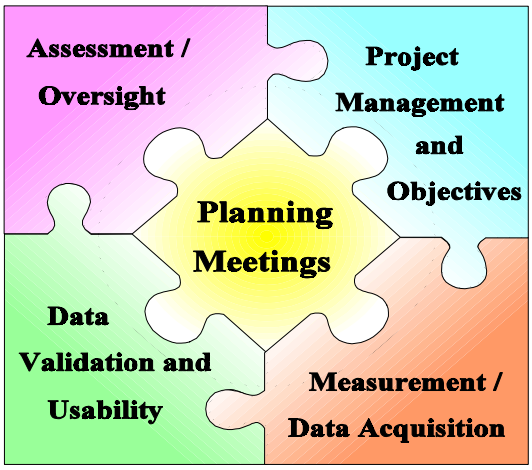
To assist in compiling critical QAPP information, two separate documents, a QAPP workbook and an example QAPP, provide blank worksheets, as well as examples of how to complete the worksheets. These QAPP Worksheets and a QAPP Summary Form can be taken to project scoping meetings and completed during the project planning stage. Subsequently, the worksheet information can be presented in tabular format in the QAPP. The worksheets are meant to serve as a guide and their use is entirely optional. However, the information requested on the worksheets must be presented in the QAPP.

Although the overall project planning process (presented in Figure 1) is presented as a linear sequence of activities, project planners are advised to revisit certain planning activities whenever necessary.

This UFP-QAPP Manual is not program-specific and is intended to be as comprehensive as possible. Since the content and level of detail in QAPPs varies according to the work being performed and the intended use of the data, parts of this UFP-QAPP Manual may not be applicable to all programs. Each of the sections and subsections in this UFP-QAPP Manual must be addressed in the QAPP to the degree appropriate for the data collection activity. To the extent practicable, information should be provided in tabular format. However, sufficient written discussion should accompany those tables to facilitate understanding.

1.3 QAPP Elements

There are four basic element groups that must be addressed in a QAPP: Project Management and Objectives (Section 2), Measurement/Data Acquisition (Section 3), Assessment/Oversight (Section 4), and Data Validation and Usability (Section 5). The four QAPP element groups represent pieces of the life cycle of a project, which are integrated through the use of planning meetings (scoping meetings).



QAPPs can be of two types:

- A "project-specific QAPP" provides a QA blueprint specific to one project or task. Project-specific QAPPs are used when projects are limited in scope and time and, in general, can be considered the Sampling and Analysis Plan (SAP)/work plan for the project.

- A "generic program QAPP" is an overarching plan that describes a program's quality objectives and documents the comprehensive set of standard operating procedures (SOPs) for sampling, analysis, QA/QC, data validation, and assessment that are specific to one program or group. In contrast to the project-specific QAPP, the generic program QAPP serves as an umbrella under which project-specific tasks may be conducted over an extended period of time. Project- or task-specific information not covered by the umbrella is documented in detailed Sampling and Analysis Plans/work plans, which use the generic program QAPP as an informational reference whenever appropriate.

Certain sections, by their nature, will require more written discussion than others. Users of this Manual should follow a "graded approach" when preparing QAPPs (see 1.4).

The information specified in Table 1 (found at the end of this chapter) must be provided in all QAPPs submitted to EPA or a delegated authority. Table 1 also provides a crosswalk between the QAPP elements, the required QAPP sections, and optional QAPP worksheets that are found in the QAPP workbook that is a companion document to this manual.

It is recommended that generic program QAPPs and project-specific QAPPs be prepared using the format described in the Manual and that they be titled accordingly. However, if some or all of the required QAPP elements are incorporated into other project planning documents (such as Sampling and Analysis Plans (SAPs), Field Sampling Plans (FSPs), Field Operations Plans (FOPs), Project Operations Plans (POPs), or general project Work Plans (WPs)), then a cross-reference table similar to Table 2 must be provided to identify where each required QAPP element is located in the inclusive project document. The reference must specify the complete document title, date, section number, page numbers, and location of the information in the inclusive document. Table 2 provides an example of such a table using a fictitious project in which several elements of the project-specific QAPP are found in existing facility-wide project planning documents. This table cross-references the required QAPP elements with information found in inclusive documents such as basewide QAPPs, Field Sampling Plans, Sampling and Analysis Plans, and others.

1.4 Graded Approach

Since the content and level of detail in individual QAPPs will vary according to the work being performed and the intended use of the data, planners will want to use a **"graded approach"** when

preparing QAPPs. A graded approach is the process of establishing the project requirements and level of effort according to the intended use of the results and the degree of confidence needed in the quality of the results. In other words, the degree of documentation, level of effort, and detail will vary based on the complexity and cost of the project. Appropriate and objective consideration should be given to the significance of the environmental problems to be investigated, the environmental decisions to be made, and the impact on human health and the environment. In some instances, documentation will consist of a concise explanation of why the particular project need not address the specified area.

1.5 Roles and Responsibilities

1.5.1 Lead Organization

Lead organizations are those entities that are responsible for all phases of the environmental data collection operation. The Lead Organization may perform the project work directly or contract for field sampling, analytical services, or data validation. The Lead Organization is responsible for ensuring that organization personnel, contractors, and/or subcontractors perform project work as prescribed in the approved QAPP. The Lead Organization for environmental data collection operations, as defined by this QAPP guidance UFP-QAPP Manual, will be a Federal agency. It will be either the actual entity that owns the facility or installation where the work is being done, or the EPA, exercising its oversight responsibility.

1.5.2 Project Manager

The Project Manager is responsible for directing and/or overseeing and coordinating all project activities for the Lead Organization. He/she is responsible for submitting QAPPs and QAPP revisions and amendments to appropriate personnel for review and approval. Refer to Figure 2 for an outline of the QAPP development process.

1.5.3 Project Team

To plan the project, the Project Manager assembles a Project Team consisting of technical personnel including data generators, QA scientists, and data users. The size of the Project Team should reflect the complexity of the project. For example, small projects may have Project Teams that consist of only two or three people.

Planning (scoping) meetings are convened to identify project and data quality objectives, decisions that must be made, project "action limits," the type and quantity of data, and how "good" the data must be (the data quality) to ensure that the right decisions are made. The Project Team defines the quality of the data by setting acceptance limits, otherwise known as measurement performance

criteria. Once the measurement performance criteria are known, the Project Team can select sampling and analytical methods that have appropriate quantitation limits and quality control limits to achieve project objectives.

The Project Team is responsible for providing all the information required by this UFP-QAPP Manual, for resolving all technical issues prior to QAPP preparation. Ultimately, it is the responsibility of the Project Team, and not the QAPP preparer alone, to design a QA "blueprint" that meets project objectives.

1.5.4 QAPP Preparation Team/Writer

The QAPP should be written by a team/person that has been involved in the project planning phase and has experience or training with QAPP preparation. Members of the QAPP Preparation Team should be experienced in many aspects of environmental science, including chemistry, engineering, hydrogeology, and risk assessment. In addition, the QAPP Preparation Team should be experienced with the sample collection procedures, analytical methods, and data evaluation and assessment procedures that will be used for the project.

1.5.5 Project Personnel

An organizational chart must clearly show the reporting relationships between the project personnel of the lead governmental organization, including contractors and subcontractors.

All project personnel are responsible for reading and understanding applicable sections of the QAPP before beginning fieldwork. All individuals that have project responsibilities must sign a Project Personnel Sign-Off Sheet to document that they have read all relevant portions of the QAPP.

All project personnel are responsible for implementing the QAPP as prescribed.

1.6 QAPP Review and Approval

1.6.1 Internal Review and Approval

The QAPP should undergo internal review at all levels. The Lead Organization is responsible for ensuring that the QAPP is accurate and complete. To that end, the Lead Organization should require that organizational personnel, contractors, and subcontractors review applicable sections of the QAPP prior to submitting it to EPA or the delegated regulatory approval authority, if applicable.

1.6.2 External Review and Approval

In accordance with EPA Order 5360.1 A2, EPA must review and approve all intramural and extramural QAPPs before the Lead Organization begins field activities. This order specifies that the authority to review and approve QAPPs may be delegated to another organization such as a State, Tribe, or other Federal agency. Delegation of this authority by EPA is contingent on that organization having an acceptable Quality System documented in an EPA-approved Quality Management Plan (QMP).

All comments provided by EPA or the approval authority must be acceptably addressed in writing prior to beginning field activities. The response document (either a revised QAPP or a letter responding to specific deficiencies) should contain complete identifying information, as it is presented on the original QAPP Title and Approval Page, with updated signatures and dates. Any revisions to the original QAPP document should be identified to expedite document review and approval.

1.7 QAPP Implementation and Modification

The approved QAPP must be implemented as prescribed; however, it is not intended to be inflexible or restrictive. Project-specific QAPPs and generic program QAPPs should be reviewed annually by the Lead Organization's Project Manager. Project-specific QAPPs must be kept current and must be revised whenever necessary, or when so directed by the approval authority, or at a minimum of every 5 years. Likewise, generic program QAPPs must be revised whenever necessary, or when so directed by the approval authority, or at a minimum of every 5 years.

When the original approved QAPP is altered in response to project needs, the QAPP must be amended. This amendment must be reviewed and approved in the same manner as the original QAPP. The amendment must contain complete identifying information, as presented on the original QAPP Title and Approval Page, with updated signatures and dates. Only after the amendment has been approved can the change be implemented.

Verbal approval of modifications may be obtained to expedite project work. Verbal approvals must be documented in telephone logs, which are retained in the project file. Subsequently, this verbally approved modification must be documented in an amendment to the QAPP and submitted to EPA (or other approval authority, if applicable) for signature approval.

1.8 QAPP Archival

All QAPPs, including reviewers' comments and responses to reviewers' comments (revised QAPPs and/or response letters addressing specific issues), must be archived in the appropriate

project/program file according to the procedures specified by the Lead Organization in their QAPP and/or QMP.

Project files must be retained for the period of time specified in the interagency agreement, memorandum of understanding (MOU), cooperative agreement, financial agreement, contract, or voluntary or enforcement consent decree, agreement, or order.

1.9 Organization of UFP-QAPP Manual

The remainder of this UFP-QAPP Manual is organized in accordance with the four elements of a QAPP:

- Project Management and Objectives
- Measurement and Data Acquisition
- Assessment and Oversight
- Data Validation and Usability

Table 1. QAPP Requirement Summarization

REQUIRED QAPP ELEMENT(S) AND CORRESPONDING QAPP SECTION(S)	OPTIONAL QAPP WORKSHEET # IN QAPP WORKBOOK	REQUIRED INFORMATION
Project Management and Objectives		
2.1 Title and Approval Page	1	- Title and Approval Page
2.2 Table of Contents and Document Format 2.2.1 Table of Contents 2.2.2 Document Control Format 2.2.3 Document Control Numbering System 2.2.4 QAPP Identifying Information	2	- Table of Contents - QAPP Identifying Information
2.3 Distribution List and Project Personnel Sign-Off Sheet	3 4	- Distribution List - Project Personnel Sign-Off Sheet
2.4 Project Organization 2.4.1 Project Organizational Chart 2.4.2 Communication Pathways 2.4.2.1 Modifications to Approved QAPP 2.4.3 Personnel Responsibilities and Qualifications 2.4.4 Special Training Requirements/ Certification	5 6 7	- Organizational Chart - Communication Pathways - Personnel Responsibilities and Qualifications Table - Special Personnel Training Requirements Table
2.5 Project Planning/Problem Definition 2.5.1 Project Planning Meetings 2.5.2 Problem Definition/Site History and Background	8	- Project Planning Meeting Documentation - Project Scoping Meeting Attendance Sheet with Agenda - Problem Definition/Site History and Background - Site Maps (historical and present)
2.6 Project Description and Schedule 2.6.1 Project Overview 2.6.2 Project Schedule	9a 9b 9c 9d 10	- Project Description - Contaminants of Concern and Other Target Analytes Table - Field Quality Control Sample Summary Table - Analytical Services Table - System Designs - Project Schedule Timeline Table

Table 1. QAPP Requirement Summarization (Continued)

REQUIRED QAPP ELEMENT(S) AND CORRESPONDING QAPP SECTION(S)	OPTIONAL QAPP WORKSHEET # IN QAPP WORKBOOK	REQUIRED INFORMATION
2.7 Project Quality Objectives and Measurement Performance Criteria 2.7.1 Project Quality Objectives 2.7.2 Measurement Performance Criteria	11	- Measurement Performance Criteria Table
Measurement/Data Acquisition		
3.1.1 Sampling Process Design 3.1.1.1 Sampling Design Rationale	12a 12b	- Sampling Design and Rationale - Sampling Locations, Sampling and Analysis Methods/SOP Requirements Table - Sample Location Map
3.1.2 Sampling Procedures and Requirements 3.1.2.1 Sampling Procedures 3.1.2.2 Sampling SOP Modifications 3.1.2.3 Cleaning and Decontamination of Equipment/Sample Containers 3.1.2.4 Field Equipment Calibration 3.1.2.5 Field Equipment Maintenance, Testing, and Inspection Requirements 3.1.2.6 Inspection and Acceptance Requirements for Supplies/Sample Containers	 13 12b 14 15	- Sampling SOPs - Project Sampling SOP Reference Table - Sampling Container, Volumes, and Preservation Table - Field Sampling Equipment Calibration Table - Cleaning and Decontamination SOPs - Field Equipment Maintenance, Testing, and Inspection Table
3.1.3 Sample Handling, Tracking, and Custody Requirements 3.1.3.1 Sample Collection Documentation 3.1.3.1.1 Field Notes 3.1.3.1.2 Field Documentation Management System 3.1.3.2 Sample Handling and Tracking System 3.1.3.3 Sample Custody	 16	- Sample Handling, Tracking, and Custody SOPs - Sample Handling Flow Diagram - Sample Container Label - Chain-of-Custody Form and Seal

Table 1. QAPP Requirement Summarization (Continued)

REQUIRED QAPP ELEMENT(S) AND CORRESPONDING QAPP SECTION(S)	OPTIONAL QAPP WORKSHEET # IN QAPP WORKBOOK	REQUIRED INFORMATION
3.2.1 Field Analytical Method Requirements 3.2.1.1 Field Analytical Methods and SOPs 3.2.1.2 Field Analytical Method/SOP Modifications 3.2.1.3 Field Analytical Instrument Calibration 3.2.1.4 Field Analytical Instrument/ Equipment Maintenance, Testing, and Inspection Requirements 3.2.1.5 Field Analytical Inspection and Acceptance Requirements for Supplies	17 18 19	- Field Analytical Methods/SOPs - Field Analytical Method/SOP Reference Table - Field Analytical Instrument Calibration Table - Field Analytical Instrument/ Equipment Maintenance, Testing, and Inspection Table
3.2.2 Fixed Laboratory Analytical Method Requirements 3.2.2.1 Fixed Laboratory Analytical Methods and SOPs 3.2.2.2 Fixed Laboratory Analytical Method/SOP Modifications 3.2.2.3 Fixed Laboratory Instrument Calibration 3.2.2.4 Fixed Laboratory Instrument/ Equipment Maintenance, Testing, and Inspection Requirements 3.2.2.5 Fixed Laboratory Inspection and Acceptance Requirements for Supplies	20 21	- Fixed Laboratory Analytical Methods/SOPs - Fixed Laboratory Analytical Method/SOP Reference Table - Fixed Laboratory Instrument Maintenance and Calibration Table

Table 1. QAPP Requirement Summarization (Continued)

REQUIRED QAPP ELEMENT(S) AND CORRESPONDING QAPP SECTION(S)	OPTIONAL QAPP WORKSHEET # IN QAPP WORKBOOK	REQUIRED INFORMATION
3.3.1 Quality Control Requirements 3.3.1.1 Sampling Quality Control 3.3.1.2 Analytical Quality Control 3.3.1.2.1 Field Analytical QC 3.3.1.2.2 Fixed Laboratory QC	 22a 22b 23a 23b 24a 24b	**Sampling** - Field Sampling QC Table - Field Sampling SOP Precision and Accuracy Table **Analytical** - Field Analytical QC Sample Table - Field Analytical Method/SOP Precision and Accuracy Table - Field Screening/Confirmatory Analysis Decision Tree - Fixed Laboratory Analytical QC Sample Table - Fixed Laboratory Method/SOP Precision and Accuracy Table
3.4.1 Data Acquisition Requirements	25	- Non-Direct Measurements Criteria and Limitations Table
3.5.1 Documentation, Records, and Data Management 3.5.1.1 Project Documentation and Records 3.5.1.2 Field Analysis Data Package Deliverables 3.5.1.3 Fixed Laboratory Data Package Deliverables 3.5.1.4 Data Reporting Formats 3.5.1.5 Data Handling and Management 3.5.1.6 Data Tracking and Control	26	- Project Documents and Records Table - Data Management SOPs
Assessment/Oversight		
4.1 Assessments and Response Actions 4.1.1 Planned Assessments 4.1.2 Assessment Findings and Corrective Action Responses 4.1.3 Additional QAPP Nonconformances	27a 27b	- Assessment and Response Actions - Project Assessment Table - Audit Checklists
4.2 QA Management Reports	28	- QA Management Reports Table

Table 1. QAPP Requirement Summarization (Continued)

REQUIRED QAPP ELEMENT(S) AND CORRESPONDING QAPP SECTION(S)	OPTIONAL QAPP WORKSHEET # IN QAPP WORKBOOK	REQUIRED INFORMATION
Data Verification/Validation and Usability		
5.1 Verification and Validation Requirements and Procedures	29a 29b	- Data Verification/Validation Process Table - Data Verification/Validation Summary Table
5.2 Data Usability/Reconciliation with Data Quality Objectives	30	- Data Usability Assessment

Note: All OPTIONAL QAPP Worksheets, when used, should be completed with project-specific information. If the OPTIONAL QAPP Worksheets are not used, the information the worksheets require must still be presented in the QAPP. In addition, other project-specific information should be provided in tabular format, as much as practicable. However, sufficient written discussion in text format should accompany these tables. Certain sections, by their nature, will require more written discussion than others. In particular, Section 3.1.1 should provide an in-depth explanation of the sampling design rationale and Sections 5.1 and 5.2 should describe the procedures and criteria that will be used to verify, validate, and assess data usability.

Table 2. Example Tracking of QAPP Requirements -- Crosswalk To Other Project Documents

REQUIRED QAPP ELEMENT(S) and CORRESPONDING QAPP SECTION(S) IN QAPP GUIDANCE	REQUIRED INFORMATION	CROSSWALK TO RELATED DOCUMENTS
Project Management and Objectives		
2.1 Title and Approval Page	- Title and Approval Page	
2.2 Table of Contents and Document Format 2.2.1 Table of Contents 2.2.2 Document Control Format 2.2.3 Document Control Numbering System	- Table of Contents	
2.3 Distribution List and Project Personnel Sign-Off Sheet	- Distribution List - Project Personnel Sign-Off Sheet	
2.4 Project Organization 2.4.1 Project Organizational Chart 2.4.2 Communication Pathways 2.4.2.1 Modifications to Approved QAPP 2.4.3 Personnel Responsibilities and Qualifications 2.4.4 Special Training Requirements/ Certification	- Organizational Chart - Communication Pathways - Personnel Responsibilities and Qualifications Table - Special Personnel Training Requirements Table	
2.5 Project Planning/Project Definition 2.5.1 Project Planning Meetings 2.5.2 Problem Definition/Site History and Background	- Project Planning Meeting Documentation - Project Scoping Meeting Attendance Sheet with Agenda - Problem Definition/Site History and Background - Site Maps (historical and present)	
2.6 Project Description and Schedule 2.6.1 Project Overview 2.6.2 Project Schedule	- Project Description - Contaminants of Concern and Other Target Analytes Table - Field and Quality Control Sample Summary Table - Analytical Services Table - System Designs - Project Schedule Timeline Table	
2.7 Data Quality Objectives and Measurement Performance Criteria 2.7.1 Data Quality Objectives 2.7.2 Measurement Performance Criteria	- Measurement Performance Criteria Table	Basewide QAPP, Section 3.0

Table 2. Example Tracking of QAPP Requirements -- Crosswalk To Other Project Documents (Continued)

REQUIRED QAPP ELEMENT(S) and CORRESPONDING QAPP SECTION(S) IN QAPP GUIDANCE	REQUIRED INFORMATION	CROSSWALK TO RELATED DOCUMENTS
Measurement/Data Acquisition		
3.1.1 Sampling Process Design 3.1.1.1 Sampling Design Rationale	- Sampling Design and Rationale - Sampling Locations, Sampling and Analysis Method/SOP Requirements Table - Sample Location Map	
3.1.2 Sampling Procedures and Requirements 3.1.2.1 Sampling Procedures 3.1.2.2 Sampling SOP Modifications 3.1.2.3 Cleaning and Decontamination of Equipment/Sample Containers 3.1.2.4 Field Equipment Calibration 3.1.2.5 Field Equipment Maintenance, Testing, and Inspection Requirements 3.1.2.6 Inspection and Acceptance Requirements for Supplies/Sample Containers	- Sampling SOPs - Project Sampling SOP Reference Table - Sampling Container, Volumes, and Preservation Table - Field Sampling Equipment Calibration Table - Cleaning and Decontamination SOPs - Field Equipment Maintenance, Testing, and Inspection Table	Basewide QAPP, Volume 3 Approved Field Sampling Plan for ____ Base, Pages 12-18 Approved Field Sampling Plan for ____ Base, Pages 24-28 Approved Field Sampling Plan for ____ Base, Pages 32-38 Basewide QAPP, Volume 2 Approved Field Sampling Plan for ____ Base, Pages 40-43
3.1.3 Sample Handling, Tracking, and Custody Requirements 3.1.3.1 Sample Collection Documentation 3.1.3.1.1 Field Notes 3.1.3.1.2 Field Documentation Management System 3.1.3.2 Sample Handling and Tracking System 3.1.3.3 Sample Custody	- Sample Handling, Tracking, and Custody SOPs - Sample Handling Flow Diagram - Sample Container Label - Chain-of-Custody Form and Seal	Basewide QAPP, Volume 1 Basewide QAPP, Volume 1 Figure 5-1, 5-2, 5-3
3.2.1 Field Analytical Method Requirements 3.2.1.1 Field Analytical Methods and SOPs 3.2.1.2 Field Analytical Method/SOP Modifications 3.2.1.3 Field Analytical Instrument Calibration 3.2.1.4 Field Analytical Instrument/ Equipment Maintenance, Testing, and Inspection Requirements 3.2.1.5 Field Analytical Inspection and Acceptance Requirements for Supplies	- Field Analytical Methods/SOPs - Field Analytical Method/SOP Reference Table - Field Analytical Instrument Calibration Table - Field Analytical Instrument/Equipment Maintenance, Testing, and Inspection Table	Basewide QAPP, Volume 4 Basewide QAPP, Volume 4

Table 2. Example Tracking of QAPP Requirements -- Crosswalk To Other Project Documents (Continued)

REQUIRED QAPP ELEMENT(S) and CORRESPONDING QAPP SECTION(S) IN QAPP GUIDANCE	REQUIRED INFORMATION	CROSSWALK TO RELATED DOCUMENTS
3.2.2 Fixed Laboratory Analytical Method Requirements 3.2.2.1 Fixed Laboratory Analytical Methods and SOPs 3.2.2.2 Fixed Laboratory Analytical Method/SOP Modifications 3.2.2.3 Fixed Laboratory Instrument Calibration 3.2.2.4 Fixed Laboratory Instrument/ Equipment Maintenance, Testing, and Inspection Requirements 3.2.2.5 Fixed Laboratory Inspection and Acceptance Requirements for Supplies	- Fixed Laboratory Analytical Methods/SOPs - Fixed Laboratory Analytical Method/SOP Reference Table - Fixed Laboratory Instrument Maintenance and Calibration Table	Basewide QAPP, Volume 5 (Organic) and Volume 6 (Metals) Basewide QAPP, Volume 5 (Organic) and Volume 6 (Metals) Basewide QAPP, Volume 5 (Organic) and Volume 6 (Metals)
3.3.1 Quality Control Requirements 3.3.1.1 Sampling Quality Control 3.3.1.2 Analytical Quality Control 3.3.1.2.1 Field Analytical QC 3.3.1.2.2 Fixed Laboratory QC	**Sampling** - Field Sampling QC Table - Field Sampling SOP Precision and Accuracy Table **Analytical** - Field Analytical QC Sample Table - Field Analytical Method/SOP Precision and Accuracy Table - Field Screening/Confirmatory Analysis Decision Tree - Fixed Laboratory Analytical QC Sample Table - Fixed Laboratory Method/SOP Precision and Accuracy Table	Approved Field Sampling Plan for ____ Base, Pages 50-52 Approved Field Sampling Plan for ____ Base, Pages 54-58 Approved Field Sampling Plan for ____ Base, Pages 60-66 Basewide QAPP, Section 6.1, Pages 6-4 to 6-5, Table 6-2 Basewide QAPP, Section 6.2, Pages 6-8 to 6-9 Basewide QAPP, Section 6.3, Pages 6-12 to 6-14, Table 6-3 Basewide QAPP, Section 6.4, Pages 6-20 to 6-23, Table 6-4
3.4.1 Data Acquisition Requirements	- Non-Direct Measurements Criteria and Limitations Table	

Table 2. Example Tracking of QAPP Requirements -- Crosswalk To Other Project Documents (Continued)

REQUIRED QAPP ELEMENT(S) and CORRESPONDING QAPP SECTION(S) IN QAPP GUIDANCE	REQUIRED INFORMATION	CROSSWALK TO RELATED DOCUMENTS
3.5.1 Documentation, Records, and Data Management 3.5.1.1 Project Documentation and Records 3.5.1.2 Field Analysis Data Package Deliverables 3.5.1.3 Fixed Laboratory Data Package Deliverables 3.5.1.4 Data Reporting Formats 3.5.1.5 Data Handling and Management 3.5.1.6 Data Tracking and Control	- Project Documents and Records Table - Data Management SOPs	Basewide QAPP, Section 8, Page 8-2, Table 8-1 Basewide QAPP, Volume 6
Assessment/Oversight		
4.1 Assessments and Response Actions 4.1.1 Planned Assessments 4.1.2 Assessment Findings and Corrective Action Responses 4.1.3 Additional QAPP Non-Conformances	- Assessment and Response Actions - Project Assessment Table - Audit Checklists	Basewide QAPP, Section 11.1, Page 11-2, Table 10-1
4.2 QA Management Reports	- QA Management Reports Table	
Data Validation and Usability		
5.1 Verification and Validation Requirements and Procedures	- Data Verification/Validation Process Table - Data Verification/Validation Summary Table	
5.2 Data Usability/Reconciliation with Data Quality Objectives	- Data Usability Assessment	

Note: Fictitious site created to demonstrate how to crosswalk QAPP requirements with other project documents.

Figure 1. Systematic Planning Process

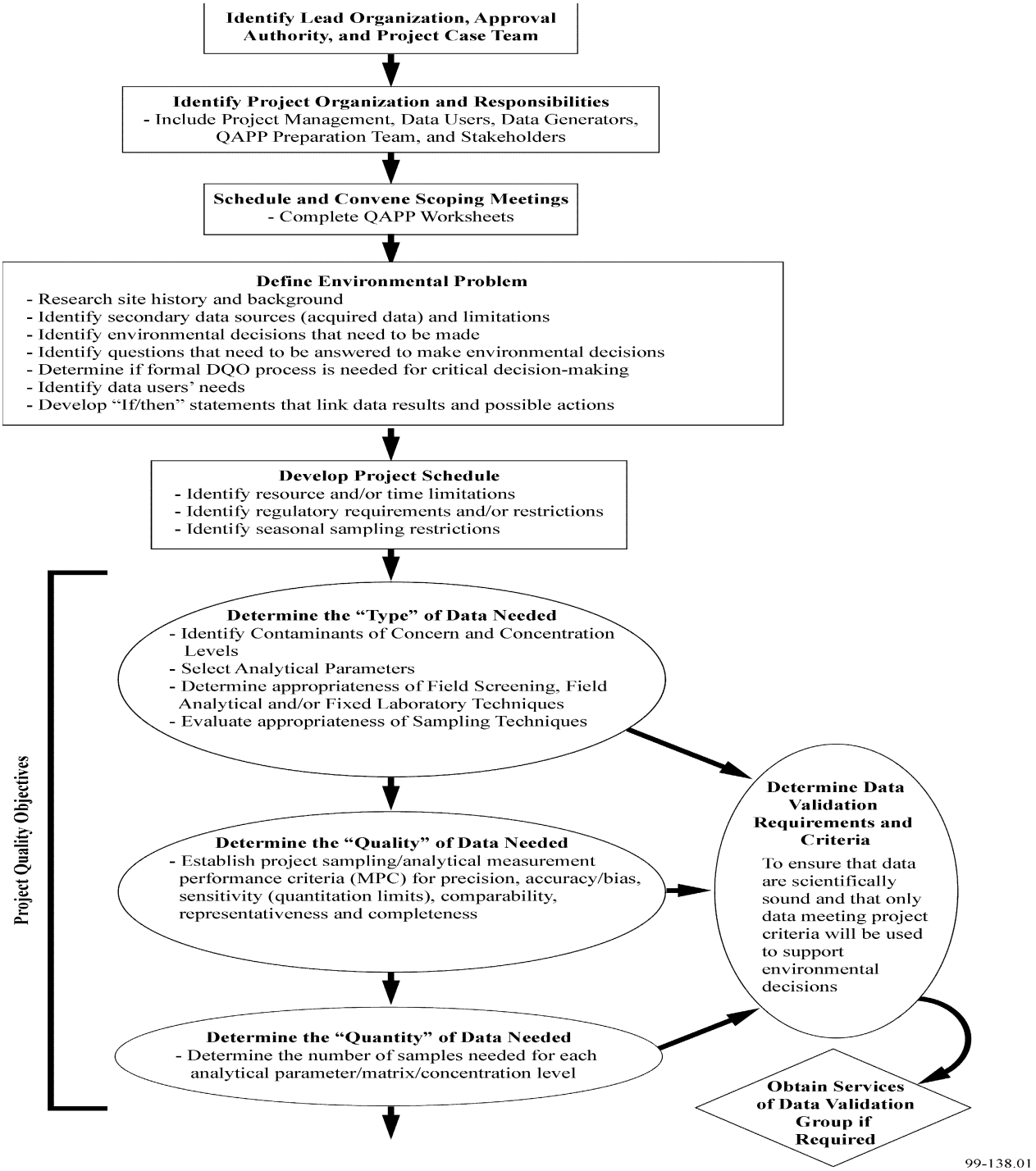
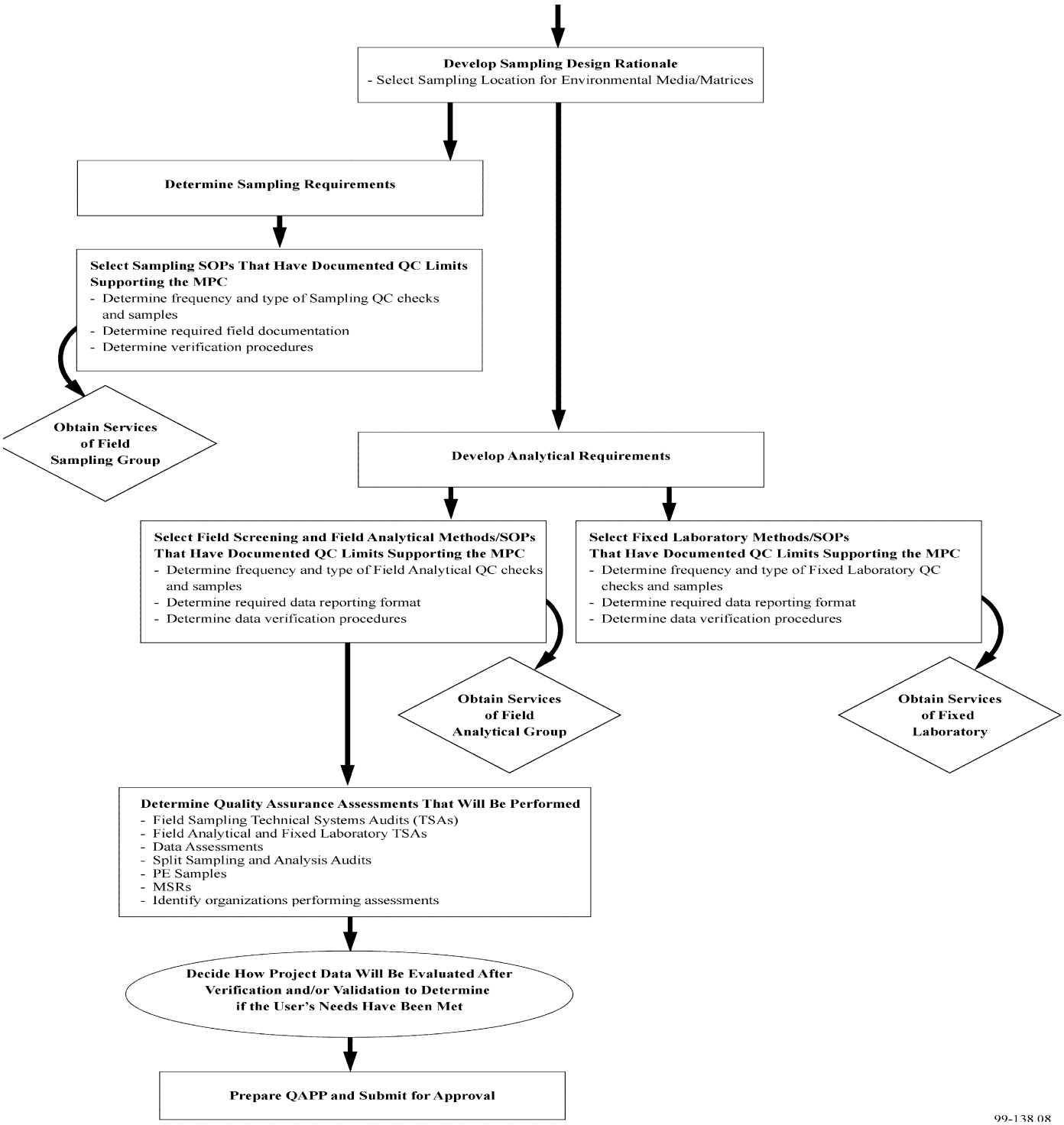


Figure 1. Systematic Planning Process (continued)



QAPP DEVELOPMENT

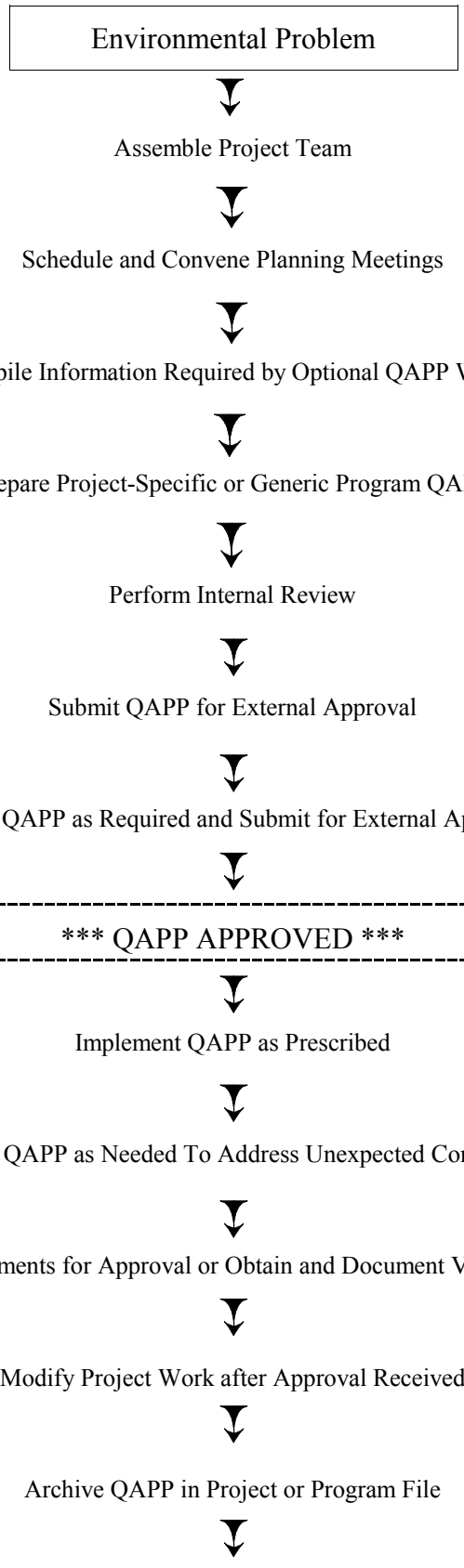


Figure 2. Outline of QAPP Development

2.0 PROJECT MANAGEMENT ELEMENTS AND OBJECTIVES

The elements of a QAPP, described in this section, ensure that the project has a defined purpose by documenting the environmental problem, the environmental questions being asked, and the environmental decisions that need to be made. They identify the project quality objectives necessary to answer those questions and support those environmental decisions. These elements also address management considerations, such as roles and responsibilities, for the project.

The following sections provide a comprehensive listing of the information that would be required in a QAPP. As much as is possible, this information should be presented in tabular format for ease of review. To assist with this process, worksheets for optional use are provided separately in a QAPP workbook. Examples of QAPPs developed for different programs can be found as separate documents.

2.1 Title and Approval Page

The Title and Approval Page is the first page of the QAPP. It documents that the QAPP has received proper approval from EPA prior to implementation.

The Title and Approval Page should contain the minimum required approvals/signatures and information shown below. (Note: In the QAPP workbook, this is Optional QAPP Worksheet #1.) The following information is required for the QAPP:

- Site Name/Project Name
- Site Location
- Document Title
- Lead Organization (Agency, State, Federal Facility, PRP, or Grantee)
- Preparer's Name and Organizational Affiliation
- Preparer's Address and Telephone Number
- Preparation Date (Day/Month/Year)
- Investigative Organization's Project Manager Signature and Printed Name/Organization/Date
- Investigative Organization's Project QA Officer Signature and Printed Name/Organization/Date Investigative Lead Organization's Project Officer Signature and Printed Name/Organization/Date
- Approval Signatures and Printed Name/Title/Date
- Other Approval Signatures
- Document Control Number

2.2 Table of Contents and Document Format

The organization of the QAPP should be easy to understand and must follow the format and section headings as described in this UFP-QAPP Manual. All tables, diagrams, charts, worksheets, if used, and other deliverables, which are itemized in this UFP-QAPP Manual, must be included as components of the QAPP and listed in the Table of Contents. If any of the required QAPP elements, or other required information, are not applicable to the project, then those QAPP elements or required information should be indicated on the QAPP Requirements table (Table 1, in Chapter 1), or some other format provided by the QAPP author, along with a justification for their exclusion.

2.2.1 Table of Contents

A Table of Contents clearly outlines the organization of the QAPP and makes project information easy to reference. Provide a Table of Contents that is comprehensive and contains the title and locations (i.e., page number, appendix or attachment number, etc.) of the following items:

- Major sections
- Subsections
- References
  Applicable reference documents may include but are not limited to the following national requirements and guidance documents:
  - ANSI, Specifications and Guidelines for Quality Systems for Environmental Data Collection and Environmental Technology Programs, American National Standard, ANSI/ASQC E4-1994.
  - Intergovernmental Data Quality Task Force, Uniform Federal Policy for Implementing Environmental Quality Systems: Evaluating, Assessing and Documenting Environmental Data Collection/Use and Technology Programs, Interim Final, Version 1, November 2000.
  - U.S. Air Force, Quality Assurance Project Plan, HQ Air Force Center for Environmental Excellence, March 1998.
  - U.S. Army Corps of Engineers, Requirements for the Preparation of Sampling and Analysis Plans, USACE EM 200-1-3.
  - U.S. Army Corps of Engineers, Technical Project Planning Guidance for HTRW Data Quality Design, USACE EM 200-1-2.
  - U.S. Army Corps of Engineers, Chemical Quality Assurance for HTRW Projects, EM-200-1-6. October 10, 1997.
  - U.S. EPA, National Enforcement Investigations Center (NEIC) Policies and Procedures, EPA-330/9-78-001-R, May 1978, Rev. December 1981. NTIS: 1-800-553-6847.
  - U.S. EPA, Guidance for the Preparation of Standard Operating Procedures for Quality-Related Operations, EPA/600/R-96/027, November 1995 (EPA QA/G-6).

  - — U.S. EPA, Guidance for the Data Quality Assessment Process: Practical Methods for Data Analysis, EPA/600/R-96/084, January 1998 (EPA QA/G-9).
  - — U.S. EPA, Guidance for the Data Quality Objectives Process, EPA/600/R-96/055, September 1994 (EPA QA/G-4).
  - — U.S. EPA, EPA Guidance for Quality Assurance Project Plans, EPA/600/R-98/018, February 1998 (EPA QA/G-5).
  - — U.S. EPA, EPA Requirements for Quality Assurance Project Plans, November 1999 (EPA QA/R-5).
  - — U.S. EPA, Region 9, Draft Laboratory Documentation Requirements for Data Validation, July 1997 (9QA-07-97).
- Appendices and/or attachments
  Applicable appendices and/or attachments include but are not limited to the following:
  - — List of standard operating procedures (SOPs) for sampling, drilling, sample preparation and analysis, etc., that are included as attachments.
  - — If the optional QAPP worksheets are used, list of completed QAPP worksheets that are included as attachments, if not included as tables in the QAPP.
  - — List of Laboratory Quality Assurance Plans (LQAPs) or Quality Assurance Manuals (LQAMs) for participating laboratories, which are included as attachments.
- List of tables
- List of figures
- List of diagrams

2.2.2 Document Control Format

Document control procedures are used to identify the most current version of the QAPP and to help ensure that only the most current version of the QAPP is used by all project participants.

Use the following document control format in the upper right-hand corner of each page of the document. Begin on the Title and Approval Page and including the Table of Contents, and all figures, tables, and diagrams.

- The title of the document (abbreviations may be used).
- The original version number or revision number, whichever is applicable, and document status (i.e., draft, interim draft, interim final, final).
- The date of the original version (i.e., draft, interim draft, interim final, final) or current revision, whichever is applicable.
- The page number in relation to the total number of pages. Alternatively, pages may be numbered as part of the total pages for a discrete section. (In the case of the second option, the Table of Contents should list inclusive page numbers for each subsection, i.e., 1-1 through 1-9, etc.).

Differentiate each revision of the QAPP with a new revision number and date.

2.2.3 Document Control Numbering System

A document control numbering system accounts for all copies of the QAPP provided to project personnel and helps to ensure that the most current version is in use. A sequential numbering system is used to identify controlled copies of the QAPP. Controlled copies should be assigned to individuals within an organization or team. Individuals receiving a controlled copy of the QAPP are provided with all revisions, addenda, and amendments to the QAPP. Those individuals in receipt of a controlled copy are responsible for removing all outdated material from circulation.

The document control system does not preclude making and using copies of the QAPP; however, the holders of the controlled copies are responsible for distributing revised or added material to update any copies within their organizations. The distribution list for controlled copies should be maintained by the organization that prepares the QAPP, and a copy of that distribution list should be provided to the Lead Organization.

2.2.4 QAPP Identifying Information

QAPP identifying information should be consolidated into one tabular format. (This is Optional Worksheet #2 in the QAPP workbook.) This information prefaces the content of the QAPP and places the document in context for the reviewer. It identifies the key project players, whether previous site work has been performed, and the program for which the current project is being performed. The identifying information required includes:

- Site Name/Project Name
- Site Location
- Site Number/Code
- Operable Unit
- Contractor Name
- Contractor Number
- Contract Title
- Work Assignment Number

1. Guidance used to prepare QAPP
2. Regulatory program (e.g., RCRA, CERCLA, CWA, etc.)
3. Approval entity
4. Generic program QAPP or a project-specific QAPP (circle one)
5. Scoping meetings/dates

6. Dates and titles of QAPP documents written for previous site work, if applicable
7. Organizational partners (stakeholders) and connection with Lead Organization
8. Data users
9. QAPP elements and/or required information not applicable to this project. (Circle the omitted QAPP elements and required information on an attached Table 1 (see Chapter 1) and explain and justify the exclusion.)

2.3 Distribution List and Project Personnel Sign-Off Sheet

2.3.1 Distribution List

The Distribution List documents those entities to whom copies of the approved QAPP and any subsequent revisions will be sent. (This is Optional Worksheet #3 in the QAPP workbook.) A complete copy of the QAPP should be sent to the Project Manager and key project personnel for the Lead Organization and EPA (or delegated approval authority). In addition, a complete copy of the original version and all revisions of the QAPP, including addenda and amendments, should be maintained on file by the Lead Organization and made available to EPA upon request. Key project personnel include Project Team members as described in Section 2.5.1 of this UFP-QAPP Manual. The Distribution List for the original version may change and should be revised for each revision submitted. Each revision of the QAPP should contain the information shown in Figure 3 below.

Figure 3. Example Table of Distribution List

QAPP Recipients	Title	Organization	Telephone Number	Document Control Number

2.3.2 Project Personnel Sign-Off Sheet

The Project Personnel Sign-Off Sheet documents that all key project personnel performing work have read the applicable sections of the QAPP and will perform the tasks as described. (This is Optional Worksheet #4 in the QAPP workbook.) Project personnel include those persons working for the Lead Organization, including contractors and subcontractors. For example, the laboratory manager who receives the QAPP should have all supervisory personnel sign off on the applicable analysis sections of the QAPP before beginning sample analysis. Other examples of key personnel include the Lead Field Sampler, Project Manager, and Laboratory QC Manager. Those in supervisory or oversight positions must communicate the requirements of the applicable portions of the QAPP to those doing work. During planning, it is the responsibility of the Project Team to

identify the personnel, by function, who must read and sign off on the applicable sections of the QAPP. Although it is not always possible to identify people by name during the early planning stages, the project team still must identify signatories by function, such as the Laboratory QC Manager. Figure 4 shows the information that must be included in the original QAPP and all revisions.

Figure 4. Project Personnel Sign-Off Sheet

Organization:

Title	Telephone Number	Signature	Date QAPP Read	QAPP Acceptable as Written Y/N

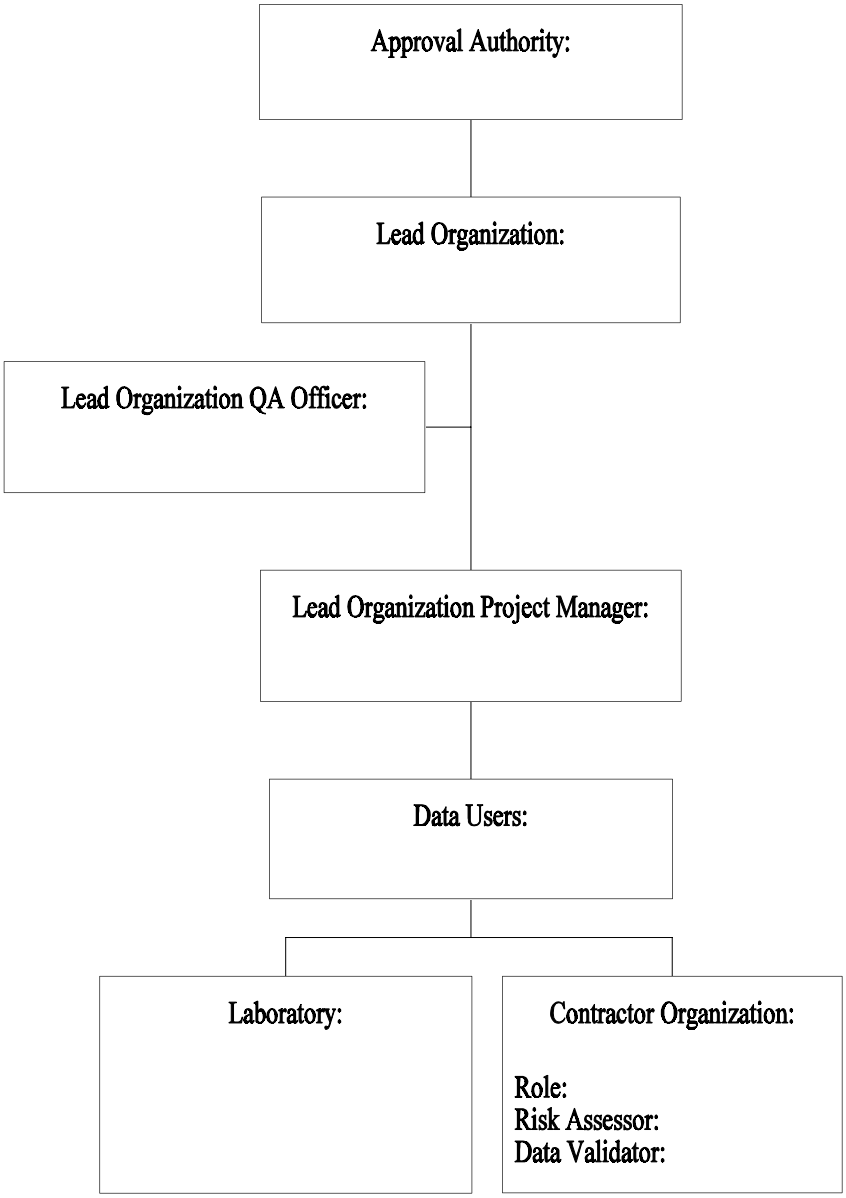
2.4 Project Organization

The "Project Organization" section of the QAPP identifies the organizations, Project Team members, and other key personnel participating in the project and describes their specific roles, responsibilities, and qualifications. This section also provides an explanation of the lines of authority, reporting relationships, and communication paths.

2.4.1 Project Organizational Chart

The Organizational Chart identifies all organizations involved in the project, including the Lead Organization and all contractor and subcontractor organizations and their telephone numbers. Include the names of all Project Managers, Project Team members, and/or Project Contacts for each organization and their telephone numbers. Refer to Section 2.5.1 of this UFP-QAPP Manual for a discussion of the Project Team. The types of information required in an organizational chart are shown in Figure 5. Figure 5 corresponds to Optional Worksheet #5 in the QAPP workbook.

Figure 5. Organizational Chart



2.4.2 Communication Pathways

One of the keys to a successful project is communication. To that end, communication pathways and modes of communication (faxes, newsletters, electronic mail, reports, etc.) should be delineated in the project planning stage and documented in the QAPP. These pathways include the points of contact for resolving field and laboratory problems and the points of contact for the flow of preliminary, screening, and final data to managers, users, and the public. Describe the proper procedures for soliciting concurrence and/or obtaining approval between project personnel, between different contractors, and/or between samplers and laboratory staff.

For example, complete the following statements:

- If field sampling will be delayed, then the Project Manager from the field sampling contractor organization will notify_____.
- No data may be released to the public until _____.
- If the laboratory fails to accurately analyze a Performance Evaluation Sample (PES), then the Project Manager from the Lead Organization will_____
  _____.

2.4.2.1 Modifications to Approved QAPP

This section documents the procedures that will be followed when any project activity originally documented in an approved QAPP requires real-time modification to achieve project goals. These project activities include, but are not limited to:

- Sampling design
- Sample collection procedures
- Sample analysis procedures
- Data assessment and reporting

All QAPP modifications must be documented and submitted for approval in the same manner as the original QAPP. The person requesting a modification, the person approving the modification, and the rationale for the modification must be documented in writing.

Describe the procedures for initiating modifications to project activities and provide this information in the QAPP. State who has the authority to initiate procedural modifications. Describe how amendments to the QAPP will be documented and submitted to EPA, or the delegated authority, for approval. All amendments to the QAPP must be incorporated into the final version of the QAPP that is maintained by the Lead Organization as a part of the official site records.

The QAPP should spell out the difference between a modification to the QAPP and a one-time deviation from the QAPP. All deviations and the reasons for the deviation must be documented in writing and incorporated into the project files. In the case of a time-sensitive issue, verbal approval for the change may be given. However, any such change must be documented in writing and included in the project files. The QAPP must specify who has the authority for requesting and for issuing verbal approvals for QAPP modifications or one-time deviations from the approved QAPP.

2.4.3 Personnel Responsibilities and Qualifications

Information on project personnel participating in responsible roles must be presented on a table by title and affiliation. The Lead Organization must certify that the key personnel meet any specific QAPP qualifications, such as laboratory certification, or that a person is a Professional Engineer (P.E.).

This table must include:

- Data users – The persons who will make decisions based on the collected data.
- Lead Organization Project Manager – Person with the responsibility and authority to allocate resources and personnel to accomplish the project tasks as documented in the QAPP.
- Lead Organization Quality Assurance Officer – Individual who provides QA oversight of project activities and who works independently of those performing project tasks.
- Project Manager(s) and/or Project Contact(s) for other organizations involved in the project (Include both prime contractors and subcontractors).
- QA Manager/Officer and/or QA Contact for other organizations involved in the project. **(Quality Assurance Manager or Project QA Officer must be independent of the group performing the task. In other words, the person responsible for checking that correct procedures are used should not be performing the tasks.)** Include both prime contractors and subcontractors.
- Project Health and Safety Officer – Include both prime contractors and subcontractors.
- Geotechnical engineers and hydrogeologists – Include both prime contractors and subcontractors.
- Field operation personnel, including field sampling coordinator, drillers, direct-push technology operators (Geoprobes, Cone Penetrometers), and field sampling personnel – Include both prime contractors and subcontractors.
- Analytical services, including on-site field analytical support and off-site fixed laboratory services – Include both prime contractors and subcontractors.
- Data validators – Include both prime contractors and subcontractors.
- Data usability assessors – Include both prime contractors and subcontractors.
- Risk assessors – Include both prime contractors and subcontractors.

Each revision of the QAPP should provide the information shown in Figure 6, which corresponds to Optional Worksheet #6 in the QAPP workbook.

Figure 6. Personnel Responsibilities and Qualifications Table

Name	Title	Affiliation	Responsibilities	Education and Experience Qualifications

2.4.4 Special Training Requirements/Certification

All project personnel must be qualified and experienced in the project tasks for which they are responsible. Certain projects require uniquely trained personnel to perform specialized field reconnaissance, sampling, field or off-site analysis, data validation, and other project functions. Provide a table showing any specialized training needed to achieve project objectives. Include training records and/or certificates as attachments to the worksheet. If training records and/or certificates are on file elsewhere, then document their location. If training records and/or certificates do not exist or are unavailable, note this information in the QAPP. If specialized training is not applicable to the project, then this section is not required. Figure 7, which shows the headings for the Special Personnel Training Requirements Table and corresponds to Optional Worksheet #7 in the QAPP workbook.

Figure 7. Special Personnel Training Requirements Table

Project Function	Specialized Training – Title of Course or Description	Training Provided By	Training Date	Personnel/ Groups Receiving Training	Personnel Titles/ Organizational Affiliation	Location of Training Records/ Certificates*

*If training records and/or certificates are on file elsewhere, document their location in this column. If training records and/or certificates do not exist or are not available, then this should be noted.

2.5 Project Planning/Problem Definition

This section of the QAPP documents project planning, identifies the environmental problem, defines the environmental questions that need to be answered, and provides background information. To ensure QAPP approval, this section must provide a historical, regulatory, and programmatic context for the project and must convey to the reviewer a clear understanding of the project background and environmental problem that exists.

2.5.1 Project Planning Meetings (Scoping Meetings)

Project scoping meetings are key to the success of any project and should be held by the Project Team prior to QAPP preparation. This section of the QAPP documents the project planning meetings held during the initial planning phase. Scoping meetings are held to define the purpose and expected results of the project; the environmental decisions that need to be made; the project quality objectives necessary to achieve expected results and support environmental decisions; the sampling, analytical, and data assessment activities that will be performed; and the final products and deliverables for the project.

Provide documentation of the meeting participants. (See Figure 8, Project Scoping Meeting Attendance Sheet, which corresponds to Optional QAPP Worksheet #8.) Identify the Project Team members who are responsible for planning the project. The actual size of the Project Team will be determined by the size and complexity of the project. Individuals responsible for the following tasks are critical to the success of the project and should be selected as Project Team members by the Lead Organization: project management, health and safety, field mobilization, sampling, geotechnical operations, sample analyses, and QA activities, including field and laboratory assessments, data validation, and data usability and risk assessments. The size of the Project Team should reflect the complexity of the project. For example, small projects may use Project Teams that consist of only two or three people. Participants should include project management, data generators (including field and laboratory personnel), data validators, quality assurance personnel, data users, and any other stakeholders.

If the Optional QAPP worksheets are being used by Project Team members, then at the initial scoping meeting the Project Team should begin by completing them using as much information as is available. The worksheets should be finalized at subsequent meetings and included as tables, diagrams, and figures in the QAPP. The QAPP should include explanatory text for tables, figures, and diagrams whenever necessary. If the worksheets are not used, the Project Team members must produce a QAPP that contains the information required by this UFP-QAPP Manual.

Data quality objectives (DQOs) define the type, quantity, and quality of data needed to answer specific environmental questions and support proper environmental decisions. DQOs should be determined and agreed upon at the initial scoping sessions. Data users must decide and agree upon when to collect samples, where to collect samples, how many samples to collect, and how accurate and precise data must be before it can be used to make decisions.

When critical environmental decisions must be made, the Project Team should follow the formal DQO process as described in the UFP-QAPP Manual document, *Guidance for the*

Request to Reviewers

What specific DoD and DOE documents are equivalent guidance documents?

Planning for Data Collection in Support of Environmental Decision-Making Using the Data Quality Objective Process, September 1994, EPA/600/R-96/055 (EPA QA/G-4). The formal DQO process as described in EPA QA/G-4 requires statistical expertise to define the amount of error acceptable when making an environmental decision and includes the following seven steps:

Step 1: State the Problem
Step 2: Identify the Decision
Step 3: Identify the Inputs to the Decision
Step 4: Define the Study Boundaries
Step 5: Develop a Decision Rule
Step 6: Specify Tolerable Limits on Decision Error
Step 7: Optimize the Design

Statistical analysis is beyond the scope of many projects; therefore, the development of formal DQOs using the process described in EPA QA/G-4 will depend on the critical nature of the environmental decisions to be made as determined by the Project Team.

For data collection activities that are either exploratory or small in nature, or where specific decisions cannot be identified, the formal DQO process is not necessary. For these projects, the Project Team should use an abbreviated DQO approach (Steps 1-4, described above) to help identify the DQOs and action limits, and to select appropriate sampling, analytical, and assessment activities. Site-specific DQOs identified at the scoping meetings should be documented in the QAPP.

Figure 8. Project Scoping Meeting Attendance Sheet

EPA Regulation Program: RCRA FIFRA TSCA CERCLA DW CWA CAA **Program: Brownfields, NPDES, etc.** **Projected Date(s) of Sampling** **Project Manager**	**Site Name** **Site Location** **CERCLA Site/Spill Identifier No.** **Operable Unit** **Other Site Number/Code** **Phase: ERA SA/SI pre-RI RI (phase I, etc.) FS RD RA post-RA (circle one)** **Other phase:**_____

Date of Meeting:
Meeting Location:

Name	Title	Affiliation	Phone #	Project Role

Meeting Purpose:
Comments:

2.5.2 Problem Definition/Site History and Background

This section frames, for the reader/reviewer, the reasons for conducting the project. It presents historic information, current site condition descriptions, and other existing data applicable to the project. This information is used to clearly define the problem and the environmental questions that must be answered for the current investigation. This information will be used to develop the project decision "If..., then..." statements in the QAPP that link data results and possible actions.

Summarize the following information in the text for this section of the QAPP:

- **The problem to be addressed by the project.** For example, "Residential drinking water wells in Toadville have shown increasing levels of benzene over the past two years."

- **The environmental questions being asked.** For example, "What is the source of the benzene contamination in the residential drinking water wells of Toadville, NH?"

- **Observations from any site reconnaissance reports.** Include pertinent existing site conditions. Information such as evident soil staining and the presence of free product materials, odors, and other known hazards should be identified and their location on-site specified. Physical objects such as metallic debris, drums, dilapidated buildings, processing equipment, and known safety hazards also should be identified and their location on-site specified.

- **A synopsis of non-direct measurement data/information from all site reports.** References to existing reports (e.g., monitoring reports and/or remedial investigation/ remedial action reports) that describe site conditions and indicator chemicals for long-term remediation and/or monitoring projects should be cited. Refer to Section B.4.1 of this UFP-QAPP Manual for a complete discussion of the identification and use of data acquired from secondary sources.

- **The possible classes of contaminants and the affected media,** as determined by historical site usage, site neighbors, industrial processes, process by-products, waste disposal practices, and possible contaminant breakdown products. The past and current chemical use information discussed in this section will be the basis for deciding the contaminants of concern to be investigated during the project.

- **The rationale for inclusion of chemical and nonchemical analyses.**

- **Information concerning various environmental indicators.** These indicators describe the present condition of the environment (water, soil, sludge, sediment, air, biota, etc.) and provide a benchmark to monitor changes in the condition of the environment.

Additionally, provide the following site maps and/or figures in this section of the QAPP:

- A detailed site map that shows the site in its present state and locates its boundaries
- A map that places the site in geographical context
- Historical maps or plans of the site prior to the investigation
- Maps identifying past and future sampling locations
- Historical and current aerial photographs

An 8 ½" x 11" copy of all site maps and drawings should be included in the QAPP in addition to larger, foldout maps and drawings.

2.6 Project Description and Schedule

This section of the QAPP provides a general overview of the activities that will be performed and how and when they will be performed based on background information/data, preplanning site visits, and scoping meetings. List these activities in the QAPP as shown in Figure 9a and provide the required overview information. (This corresponds to Optional Worksheet #9a in the QAPP workbook.) Specific details for the individual project activities will be provided in later sections of the QAPP.

Figure 9a. Project Description Sections

Sampling Tasks, Analysis Tasks, Quality Control Tasks, Secondary Data, Data Management Tasks, Documentation and Records, Data Packages. Assessment/Audit Tasks, Data Verification and Validation Tasks, Data Usability Assessment Tasks.

2.6.1 Project Overview (Outcome of Project Scoping Activities)

Through its project planning, the Project Team reaches agreement on the purpose of the project, the environmental questions that are being asked, and the environmental decisions that must be made. The Project Team decides on the project quality objectives, that is, they specify the type, quantity, and quality of data needed to ensure that project data can be used for the intended purpose: to answer specific environmental questions and support environmental decisions.

The Project Team also agrees on what environmental indicators and/or contaminants of concern (COCs) must be measured and determines the other target analytes that will be measured. Generally these other target analytes can be measured using the same analytical methods that are used to determine the COCs. The other target analytes have the potential of becoming COCs after site characterization.

The Project Team also determines criteria for how "good" the measure data must be to achieve the project objectives and documents those measurement performance criteria (MPC) in the QAPP. The information should be presented in tabular format, such as that shown in Figure 9b, Contaminants of Concern and Other Target Analytes Table. Provide separate tables for each medium/matrix, concentration level, and analytical parameter. Figure 9b corresponds to Optional Worksheet #9b in the QAPP workbook.

Figure 9b. Contaminants of Concern and Other Target Analytes Table (Reference Limits and Evaluation Table)

Medium/Matrix:
Analytical Parameter:
Concentration Level:

Analyte	CAS Number	Project Action Limit (Units) (wet or dry weight)	Project Quantitation Limit (Units) (wet or dry weight)	Analytical Method		Achievable Laboratory Limits	
				MDLs[1]	Method QLs[1]	MDLs[2]	QLs[2]

[1]Analytical method MDLs and QLs documented in validated methods. QLs are usually 3-10 times higher than the MDLs.
[2]Achievable MDLs and QLs are limits that an individual laboratory can achieve when performing a specific analytical method.

Note: Achievable method detection limits (MDLs) and quantitation limits (QLs) (as shown on Figure 9b), also referred to as practical quantitation limits (PQLs), represent the MDLs and QLs that an individual laboratory can achieve when performing a specific analytical method. An individual laboratory may not always be able to achieve the MDLs and QLs that are published in a validated method. In other words, even though a published analytical method may meet project requirements, this does not ensure that a laboratory can perform the analytical method satisfactorily. Therefore, laboratory MDLs and QLs/PQLs must be documented in the laboratory's SOP for each analytical method that the laboratory will perform for the project.

Project-required quantitation limits and Action Limits must be established prior to the selection of sampling and analytical methods. To compensate for potential analytical inaccuracy at the quantitation limit, project-required QLs should be at least two to five times less than the Action Limits, if achievable.

The QLs from individual methods and laboratories are evaluated relative to project-required Action Limits to determine their suitability to meet project quality objectives. If the published method QL exceeds the Action Limit for a COC or other target analyte, then that analytical method is unacceptable for the analysis of that analyte. (However, if a laboratory has modified the published method to achieve QLs that are less than the Action Limits, and documented this modification in its laboratory SOP, then that laboratory SOP *might* constitute an acceptable method. Refer to Section 2.7.2 for additional guidance on quantitation limits.)

If the laboratory and method cannot achieve the project goals for QL and Action Limits, one of the following options must be pursued:

Option 1 - Use a different laboratory.
Option 2 - Use an alternative analytical method or a modified method.
Option 3 - Accept a higher level of uncertainty for data falling between the MDL and QL.
Option 4 - Adjust the project Action Limits to achieve the desired level of laboratory performance.

2.6.1.1 Sampling Tasks

Briefly explain the rationale for sampling specific media/matrices, concentration levels, and analytical parameters of concern and the rationale for the sampling design selected (including the logic used to determine sample locations and the type, number, and frequency of field samples). Refer sample locations to historical and current site maps (Section 2.5.2). Include any additional maps, if necessary, to delineate site boundaries geographically, both horizontally and vertically. Provide complete details of the sampling rationale, process design, and sampling tasks in Section 3.1.1 of the QAPP.

Briefly describe the sampling methods that will be used. Describe any new or innovative sampling techniques that will be employed. Also, describe any specialized equipment and/or associated operators that will be required. Provide complete descriptions of the sampling methods and associated sampling quality control, and identify all sampling, sample handling, and custody SOPs in Sections 3.1.2, 3.1.3, and 3.1.3.3 of the QAPP. Provide a summary table showing the number of field QC samples that will be collected for each medium analytical parameter and concentration level as illustrated in Figure 9c, the Field Quality Control Sample Summary Table. Figure 9c corresponds to Optional Worksheet #9c in the QAPP workbook.

Figure 9c. Field Quality Control Sample Summary Table

Medium/ Matrix	Analytical Parameter	Concentration Level	Analytical Method/ SOP Reference	No. of Sampling Locations[1]	No. of Field Duplicate Pairs	Organic		Inorganic		No. of VOA Trip Blanks	No. of Bottle Blanks	No. of Equip. Blanks	No. of Cooler Temp. Blanks	No. of PE Samples	Total No. of Samples to Lab
						No. of MS	No. of MSD	No. of Duplicates	No. of Spikes						

[1]**If samples will be collected at different depths at the same location, count each discrete sampling depth as a separate sampling location/station.**

2.6.1.2 System Designs

Provide a brief description of activities for projects that involve remediation and/or monitoring engineering designs (e.g., groundwater extraction systems or soil/water/air treatment systems). Provide complete descriptions of the treatment/monitoring systems and include all treatment train schematics and process diagrams in Section 3.1.1 of the QAPP.

2.6.1.3 Analytical Tasks

Briefly describe the analytical tasks to be performed, including the sample media/matrices, analytical parameters, and concentration levels, and provide a general description of analytical methods. Clearly differentiate analytical tasks that will be performed in the field from those performed in a fixed laboratory. Also, differentiate the data produced for each analytical task into "definitive" versus "screening" use categories. Describe any new analytical techniques that will be employed and explain how the new technique will provide improved data over traditional/standard methods. Also, describe any specialized equipment and/or analysts that will be required. Provide complete detailed descriptions of the analytical tasks and associated analytical quality control, and identify all analytical SOPs and methods in Sections 3.2.1, 3.2.2, and 3.3.1 of the QAPP.

Identify the analytical services that will be provided for the project.

Complete an Analytical Services Table with headings similar to those shown in Figure 9d. Identify the organization(s)/ laboratories that will provide the analytical services (for all field screening, field analytical, and fixed laboratory analytical work, including all prime laboratories, subcontractor laboratories, and backup laboratories) by medium/matrix, analytical parameter, and concentration level. Figure 9d corresponds to Optional Worksheet #9d in the QAPP workbook.

Figure 9d. Analytical Services Table

Medium/ Matrix	Analytical Parameter	Concentration Level	Analytical Method/SOP	Data Package Turnaround Time	Laboratory/Organization (Name and Address: Contact Person and Telephone Number)	Backup Laboratory/Organization (Name and Address: Contact Person and Telephone Number)

2.6.1.4 Data Verification and Validation Tasks

Briefly discuss how data will be verified internally and validated externally and how analytical error will be assessed. If data will not be validated, then document this fact and provide justification in this section. Provide a complete description of the data verification and validation tasks and procedures in Section 5.1 of the QAPP.

2.6.1.5 Quality Assurance Assessments

Include a short description of the quality assurance assessments that will be performed during the course of the project and the frequency at which each will be performed. If assessments are not planned, then document this fact and provide justification in this section. Provide a complete description of the planned assessments in Section 4.1 of the QAPP.

2.6.1.6 Data Usability Assessments

Include a short description of how validated project data will be reconciled with the project quality objectives. Provide a complete description of data usability assessments in Section 5.2 of the QAPP.

2.6.1.7 Records and Reports

Summarize the project documents, records, and reports that will be compiled and/or generated as part of the project and those that will be maintained in the site files. Itemize and describe all project documents, records, and reports that will be compiled and/or generated during the course of this project in Sections 3.4.1, 3.5.1, and 4.2 of the QAPP.

2.6.2 Project Schedule

Provide a schedule of the work to be performed using a timeline or tabular format such as that shown in Figure 10. The timeline must include the start and completion dates for all project activities. Include the quality assurance assessments that will be performed during the course of the project (the deliverable column shown in Figure 10). Schedule sufficient time for document review and

implementation of effective corrective actions. Figure 10 corresponds to Optional Worksheet #10 in the QAPP workbook.

Figure 10. Project Schedule Timeline Table

Activities	Dates (MM/DD/YY)		Deliverable	Deliverable Due Date
	Anticipated Date(s) of Initiation	Anticipated Date of Completion		

In addition to the timeline, describe the procedure for notifying project participants concerning project schedule delays. Identify, by job function and organization name, the personnel responsible for providing as well as receiving such notification, and the personnel responsible for approving schedule delays.

Discuss all resource and time constraints, and identify all regulatory requirements and/or restrictions, that will affect the project schedule. Discuss all seasonal sampling restrictions and considerations.

2.7 Project Quality Objectives and Measurement Performance Criteria

This section of the QAPP documents the environmental decisions that need to be made and the level of data quality needed to ensure that those decisions are based on sound scientific data. Project quality objectives must be determined by the Project Team utilizing the Systematic Planning Process as outlined in Figure 1 (in the Introduction) and Section 2.7.1 below.

2.7.1 Project Quality Objectives

Systematic planning is a planning process that is based on the scientific method and includes concepts such as objectivity of approach and acceptability of results. Systematic planning is based on a commonsense, graded approach to ensure that the level of detail in planning is commensurate with the importance and intended use of the work, and the available resources. This framework promotes communication between all organizations and individuals involved in an environmental program. Through a systematic planning process, a team can develop acceptance or performance criteria or project quality objectives (PQOs) for the right type, quality, and quantity of the data collected and for the quality of the decision. PQOs ensure that the proper data are collected and generated to answer questions regarding a specific environmental problem.

The systematic planning process also ensures that appropriate project decisions are made. The planning process may incorporate the formal DQO process, as described in EPA QA/G-4, when critical environmental decisions are required, such as selecting between two clear alternative

conditions (e.g., decision-making or compliance with a standard). However, for most monitoring and investigative data collection projects, an abbreviated DQO process should suffice.

A systematic planning process results in qualitative and quantitative statements that answer the following questions:

- Who will use the data?
- What will the data be used for?

  Specify the anticipated uses of the data. Simple, clear statements should be used to describe the data uses, as in the following statements: "These data will be used to determine the nature and extent of contamination." "These data will be used to determine the health risks to children ages 1-6 who reside on the site and who might be exposed to surface soils in the area." "These data will be used to determine regulatory compliance with CERCLA statutes." "These data will be used to assess the quality of the data generated by Potentially Responsible Parties (PRPs)." "These data will be used to identify the source of high nutrient loadings in the Meandering River."
- What type of data are needed?

  Identify contaminants of concern and other target analytes and select analytical parameters; determine appropriateness of field screening, field analytical, and/or fixed laboratory techniques; evaluate appropriateness of different types of sampling techniques (e.g., low flow sampling).
- How "good" do the data need to be in order to support the environmental decision?

  Establish criteria for performance measures, including precision, accuracy/bias, sensitivity (quantitation limits), data comparability, representativeness, and completeness.
- How much data are needed?

  Determine the number of samples needed for each analytical parameter/matrix/and concentration level.
- Where, when, and how should the data be collected/generated?
- Who will collect and generate the data?
- How will the data be reported?

2.7.2 Measurement Performance Criteria

Once the environmental decisions have been identified, data users and QA personnel can determine the project quality objectives, including the measurement performance criteria, that must be satisfied in order to support defensible decisions. (See Figure 14 or Worksheet #11 in the QAPP workbook for example headings from a Measurement Performance Criteria Table.)

Document the performance criteria selected for the project-specific sampling measurement systems that will ensure that project objectives are met. For example, appropriate performance criteria should be identified to ensure that monitoring wells will be installed correctly and will yield representative samples.

Document the performance criteria selected for the analytical measurement systems that will ensure that project objectives are met. The following paragraphs provide examples of developing performance criteria for the project-specific analytical measurement systems.

Measurement performance criteria should be determined for each matrix, analytical parameter, concentration level, and analyte, if applicable. These criteria are for precision, accuracy/bias, representativeness, comparability, sensitivity, quantitation limits, and completeness. These parameters indicate the qualitative and quantitative degree of quality associated with measurement data and, hence, are also referred to as data quality indicators (DQIs). DQIs are also referred to as the PARCC parameters. (DQIs should not be confused with the overall project quality objectives that are developed using the formal DQO process.)

A discussion of DQIs for which performance criteria should be developed follows.

2.7.2.1 Precision

Determine quantitative measurement performance criteria for acceptable field and laboratory precision for each matrix, analytical parameter, and concentration level. Also determine analyte-specific measurement performance criteria, if applicable. Determine what QA/QC activities and/or QC checks or samples will be performed or analyzed to measure precision for each matrix, analytical parameter, and concentration level.

Precision is the degree of agreement among repeated measurements of the same characteristic (analyte, parameter, etc.) under the same or similar conditions. Precision data indicate how consistent and reproducible the field sampling or analytical procedures have been. "Overall project precision" is measured by collecting data from replicate field samples. Precision specific to the laboratory is measured by analyzing laboratory replicate samples. Comparing overall project precision and laboratory precision will help to identify sources of imprecision if a problem exists.

If only two replicate samples are collected and analyzed, then these samples are referred to as field duplicates. If two aliquots of the same sample are prepared and analyzed by a laboratory, then these samples are referred to as laboratory duplicates. If two aliquots of the same prepared sample are analyzed in duplicate, then these samples are referred to as analytical duplicates. Duplicate precision is evaluated by calculating a Relative Percent Difference (RPD) using the following equation (the smaller the RPD, the greater the precision):

$$RPD = \frac{|x_1 - x_2|}{\frac{x_1 + x_2}{2}} \times 100\%$$

where:

x_1 = original sample concentration
x_2 = replicate sample concentration

If more than two replicate samples are collected and analyzed, then these samples are referred to as field replicates. If two or more aliquots of the same sample are prepared and analyzed by a laboratory, then these samples are referred to as laboratory replicates. If more than two aliquots of the same prepared sample are analyzed in replicate, then these samples are referred to as analytical replicates. Replicate precision is evaluated by calculating the Relative Standard Deviation (RSD), also referred to as the coefficient of variation (V), of the samples using the following equation (the smaller the RSD, the greater the precision):

$$\%RSD = \frac{S}{mean} \times 100\%$$

where:

$$S = \sqrt{\frac{\sum_{i=1}^{n} (x_i - \bar{x})^2}{n-1}}$$

x_i = each individual value used for calculating the mean
$\bar{x}$ = the mean of n values
n = the total number of values

2.7.2.2 Accuracy/Bias

Determine quantitative measurement performance criteria for acceptable accuracy/bias for each matrix, analytical parameter, and concentration level. Also determine analyte-specific measurement performance criteria, if applicable. Determine what QA/QC activities and/or QC checks or samples

will be performed or analyzed to measure accuracy/bias for each matrix, analytical parameter, and concentration level.

Accuracy is the extent of agreement between an observed value (sample result) and the accepted, or true, value of the parameter being measured. Accuracy is frequently used synonymously with bias. Specifically, the term "bias" describes the systematic or persistent error associated with a measurement process. Both terms are used interchangeably in this document.

Analyte accuracy/bias can be evaluated using different types of QC samples. For example, a standard reference material (SRM) or a laboratory control sample (LCS), containing a known concentration of analyte(s) spiked into blank water or other blank matrices, provides information about how accurately the laboratory (analysts, equipment, reagents, etc.) can analyze for a specific analyte(s) using a selected method. Also, single-blind and double-blind performance evaluation (PE) samples provide information on how accurately the laboratory can analyze a specific analyte using a selected method. The cumulative laboratory and method accuracy/bias is calculated as a percentage using the following equation:

$$Accuracy/Bias = \frac{Measured\ Value}{True\ Value} \times 100\%$$

Because environmental samples contain interferences (i.e., other compounds that may interfere with the analysis of a specific analyte), the accuracy/bias for a specific analyte should be evaluated in relation to the sample matrix. This is done by analyzing matrix spike samples. A known concentration of the analyte is added to an aliquot of the sample. The difference between the concentration of the analyte in the unspiked sample and the concentration of the analyte in the spiked sample should be equal to the concentration of the analyte that was spiked into the sample. The spike recovery is calculated as a percentage using the following equation:

$$\%Recovery\ Accuracy/Bias = \frac{Spiked\ Sample\ Conc.\ \&\ Unspiked\ Sample\ Conc.}{Spiked\ Conc.\ Added} \times 100\%$$

Frequently, matrix spike samples are prepared and analyzed in duplicate, especially for organic analyses, to provide sufficient precision and accuracy data to evaluate achievement of project quality objectives.

Note: In general, published methods provide precision and accuracy/bias statements that are supported by data generated during method validation studies. Additionally, laboratories should track and maintain records of precision and accuracy/bias trends for their QC samples (such as laboratory duplicates/replicates, SRMs, LCSs, and matrix spike analyses) and include acceptable

precision and accuracy/bias ranges in their analytical SOPs. Published QC data, and familiarity with routine method performance, will allow project planners to choose project-required measurement performance criteria that are technically feasible.

2.7.2.3 Representativeness

Determine qualitative measurement performance criteria for acceptable representativeness for each matrix, analytical parameter, and concentration level. Also determine analyte-specific measurement performance criteria, if applicable. Determine what QA/QC activities and/or QC checks or samples will be performed or analyzed to measure representativeness for each matrix, analytical parameter, and concentration level.

Representativeness is a qualitative term that describes the extent to which a sampling design adequately reflects the environmental conditions of a site. It takes into consideration the magnitude of the site area represented by one sample and assesses the feasibility/reasonableness of that design rationale. Representativeness also reflects the ability of the sample team to collect samples, and the ability of the laboratory personnel to analyze those samples, in such a manner that the data generated accurately and precisely reflect the conditions at the site. In other words, a discrete sample (that is collected and then subsampled by the laboratory) is representative when its measured contaminant concentration equates to the contaminant concentration of some predefined vertical and horizontal spatial area at the site. Consider the issues of sample homogeneity, and sampling and subsampling variability, when developing criteria for representativeness. The use of statistical sampling design and standardized SOPs for sample collection and analysis helps to ensure that samples are representative of site conditions.

2.7.2.4 Comparability

Determine quantitative measurement performance criteria for acceptable data comparability for each matrix, analytical parameter, and concentration level. Also determine analyte-specific measurement performance criteria, if applicable. Determine what QA/QC activities and/or QC checks or samples will be performed or analyzed to measure data comparability for each matrix, analytical parameter, and concentration level.

Address such issues as consistency in sampling and analytical procedures within and between data sets. For example, monitoring well-sampling SOPs should require that well casings be notched or permanently marked so that the water level measurement is taken from the same spot for each sampling event. This will help to ensure data comparability for repeated water level measurements.

2.7.2.4.1 *Oversight Split Sampling Data Comparability*

Whenever oversight split sampling and analysis are performed (e.g., EPA oversight of the Lead Organization and its contractors/subcontractors), criteria to compare EPA-generated data with the data generated by the Lead Organization must be established and documented in the oversight QAPP prior to data collection.

Comparability criteria should be determined for each matrix, analytical parameter (and analyte, if applicable), and concentration level. Oversight split sampling comparability criteria must specify the following:

1. Acceptable percent difference (%D) for individual analyte comparisons (for combinations of nondetects, detects close to the QLs, and detects sufficiently greater than the QLs).
2. Acceptable percentage for number of analytes (per matrix, analytical parameter, and concentration level) with acceptable percent differences versus total number of percent differences (per matrix, analytical parameter, and concentration level).
3. The acceptable magnitude and direction of bias for comparisons performed in 1 and 2 above.
4. Acceptable overall comparability criteria for all data generated for use in the project.

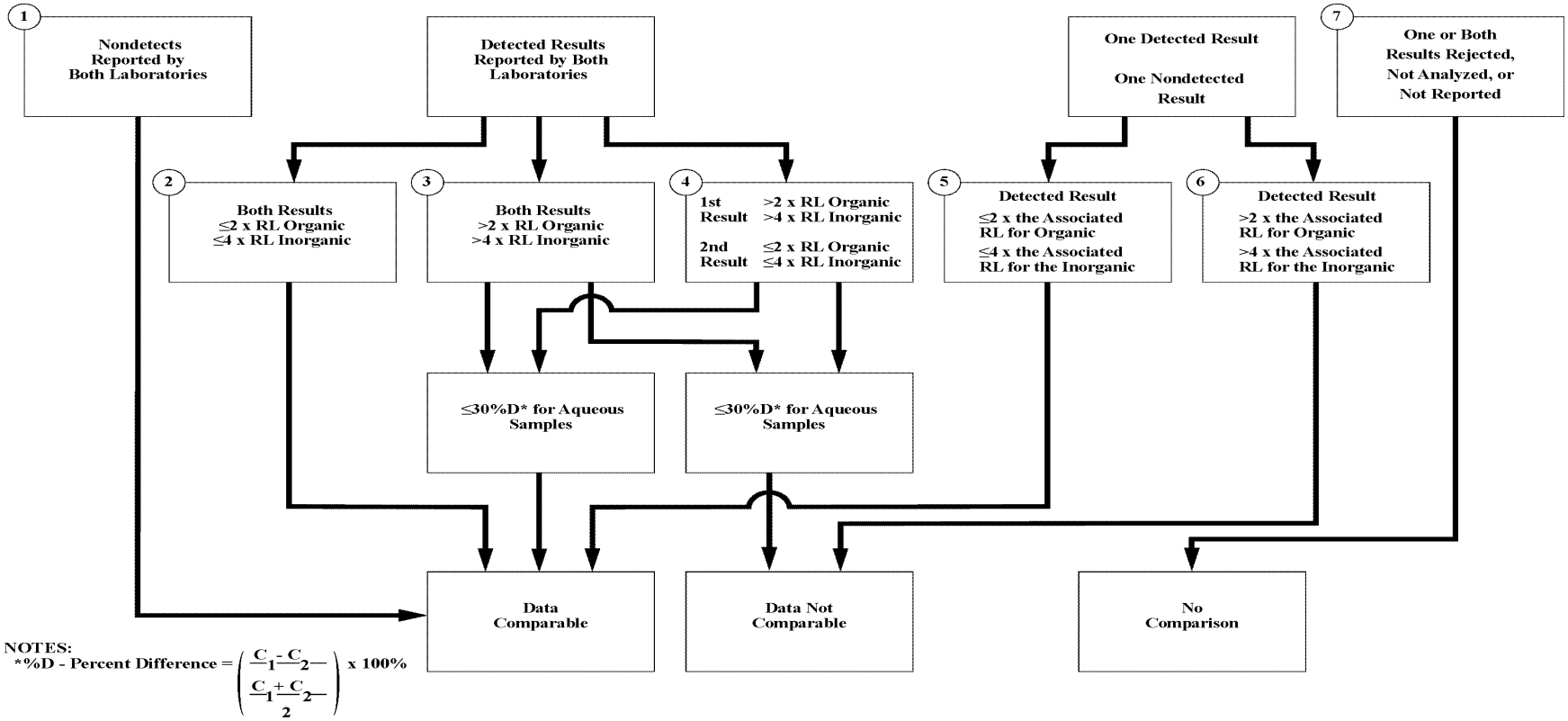
Whenever split sampling is performed, a comparability flow diagram must be included in this section of the QAPP. An example of a flow diagram is provided in Figure 11.

2.7.2.4.2 *Field Screening/Confirmatory Split Sampling Data Comparability*

Whenever full protocol analysis is performed to confirm field screening results, comparability criteria must be established and documented in the QAPP prior to data collection. Comparability criteria should be determined for each matrix, analytical parameter (and analyte, if applicable), and concentration level.

The comparability of field screening data generated on-site and split sample confirmation data generated in a fixed or field laboratory using conventional full-protocol analytical methods is the most important factor for determining whether field screening data will meet the project objectives and be usable for project decision-making. The conventional full-protocol analytical methods that are used to confirm field screening results must be scientifically valid and well-documented methods that have been routinely accepted by regulators, since data comparability decisions are based on a limited number of samples analyzed by those conventional full-protocol methods.

Figure 11. Example: Data Comparison Flow Diagram and Criteria for Individual Aqueous Split Sample Results (generated using equivalent analytical methods and achieving equivalent QLs)



NOTES:
*%D - Percent Difference = $\left(\frac{C_1 - C_2}{\frac{C_1 + C_2}{2}} \right) \times 100\%$

RL = Reporting Limit is the Quantitation Limit adjusted for any necessary sample dilutions, sample volume deviations, and/or extract/digestate volume deviations.

99-138.06

Figure 12, Comparability Determination, illustrates two approaches that can be used for determining the comparability of field screening and confirmatory data. One approach involves the generation and application of predesign correlation factors to adjust field screening sample results prior to performing data comparability calculations. Correlation factor adjustment of field screening sample results can be critical when a one-to-one correlation does not exist for data generated with the field screening and confirmatory methods (depending on differences in methods selectivity, sensitivity, precision, and accuracy, as well as the relationship of the achievable quantitation limits to the project Action Limits).

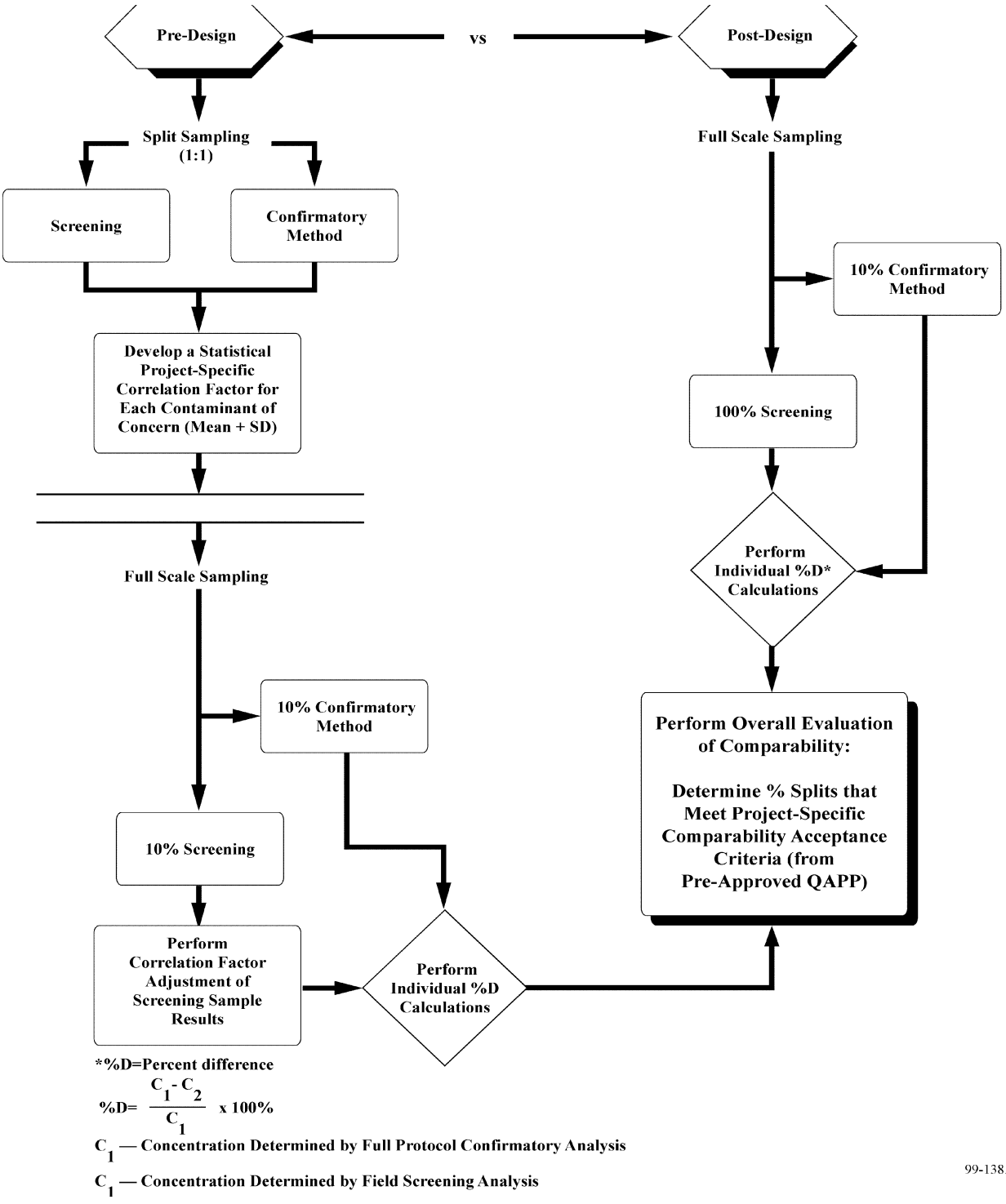
The other approach does not use correlation factor adjustment of field screening sample results prior to performing data comparability calculations. Note that comparability calculations, performed with field screening and confirmatory data for which correlation factors have not been generated and/or applied, may result in project-specific comparability criteria being exceeded (especially if these criteria are tight).

Both approaches require that data comparability acceptance requirements be developed and documented in an approved project QAPP prior to initiation of field sampling activities.

When developing comparability acceptance criteria for field screening and confirmatory data, the following issues must be considered:

- Are the screening and confirmatory methods based on the same analytical principles? If the screening and confirmatory methods measure target analytes using different principles, then a one-to-one correlation should not be assumed.
- Do the screening and confirmatory methods analyze for the same list of target analytes? If not, then a one-to-one correlation should not be assumed.
- Do the screening and confirmatory methods report to the same QL? If not, then how will data reported below the QL of either one of the methods be handled? Also, are the QLs for the screening and confirmatory methods significantly less than the project Action Limits?
- Do the screening and confirmatory methods have the same extraction efficiencies, use the same sample volumes, and perform similar sample pretreatment and sample cleanup? These differences may also account for correlations that are not one-to-one.
- How will percent moisture be accommodated for both screening and confirmatory samples?
- Are the calibration procedures the same for the screening and confirmatory methods; that is, will standard calibration curves be generated, or single point calibrations?

Figure 12. Comparability Determination



Field screening/confirmatory comparability criteria must specify the following:

1. Acceptable percent differences for individual analyte comparisons (for combinations of nondetects, detects close to the QLs, and detects sufficiently greater than the QLs).
2. Acceptable percentage for number of analytes (per matrix, analytical parameter, and concentration level) with acceptable percent differences versus total number of percent differences (per matrix, analytical parameter, and concentration level).
3. The acceptable magnitude and direction of bias for comparisons performed in 1 and 2 above.
4. Acceptable overall comparability criteria for all data generated for use in the project.

Whenever field screening/confirmatory split sampling is performed, a comparability flow diagram must be included in this section of the QAPP. Multiple flow diagrams may be needed to address QL differences between screening and full-protocol methods.

2.7.2.5 Sensitivity

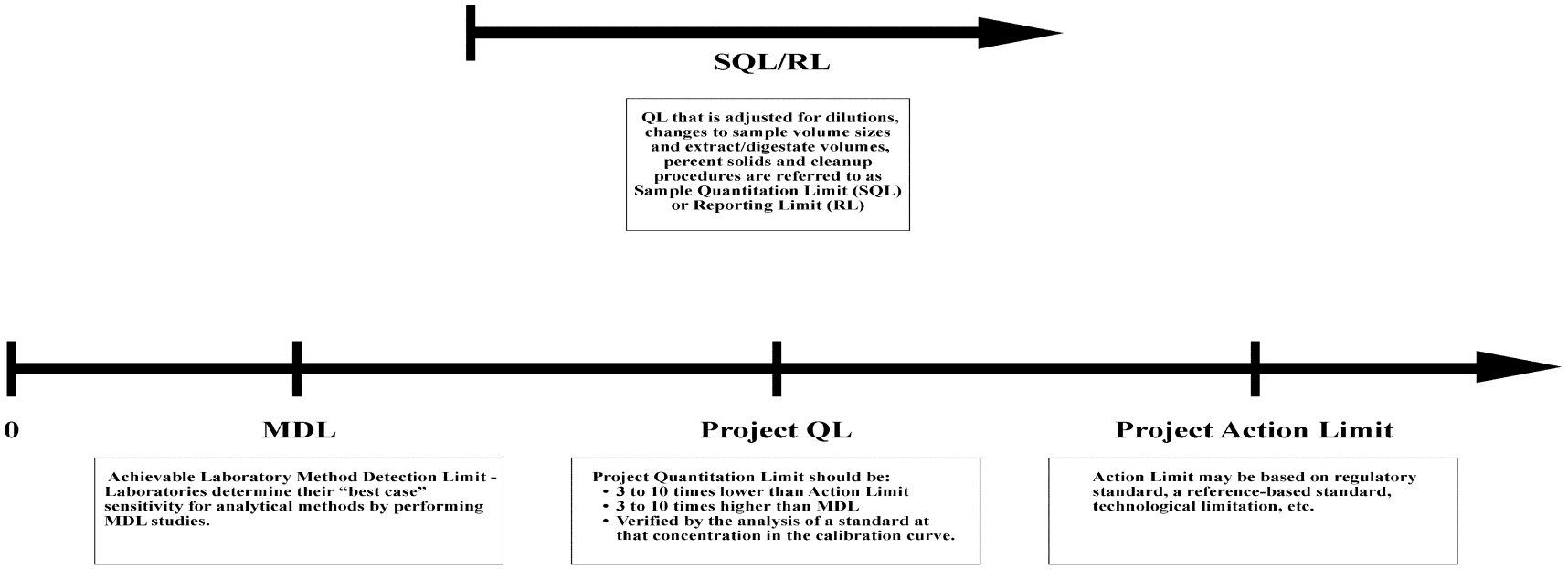
Determine quantitative measurement performance criteria for acceptable sensitivity to ensure that QLs can be routinely achieved for each matrix, analytical parameter, and concentration level. Also determine analyte-specific measurement performance criteria, if applicable. Identify which QA/QC activities and/or QC checks or samples will be performed or analyzed to measure sensitivity.

Sensitivity is the ability of the method or instrument to detect the contaminant of concern and other target compounds at the level of interest. Method and instrument sensitivity may be evaluated by preparing and analyzing a Laboratory Fortified Blank (LFB). An LFB is a blank matrix that is spiked at the quantitation limit with the contaminants of concern. Sensitivity may be measured by calculating the percent recovery of the analytes at the quantitation limit.

2.7.2.6 Quantitation Limits

Document the project-required quantitation limits for each matrix, analytical parameter, concentration level, and analyte. Differentiate between project Action Limits and project-required quantitation limits. The Action Limit for a contaminant of concern or other target compound is the numerical value that causes the decision-maker to choose one of the alternate actions. It may be a regulatory threshold such as MCL, a risk-based concentration level, a reference-based standard, or a technological limitation. Because of uncertainty at the quantitation limit, project-specific QLs should be at least one-third of the Action Limit, and ideally one-tenth of the Action Limit. Refer to Figure 13 for a representation of these relationships. Also differentiate between MDLs and QLs that are documented in a published analytical method and MDLs and QLs that an individual laboratory can routinely achieve.

Figure 13. Determining Project Quantitation Limits



The following issues should be considered when selecting project-specific QLs:

- A laboratory MDL is a statistically derived detection limit and should be lower than the concentration at which the laboratory can quantitatively report. Laboratories determine their "best case" sensitivity for analytical methods by performing MDL studies.

- The QL is the minimum concentration of an analyte that can be routinely identified and quantified above the MDL by a laboratory. QLs should be at least 3 times the achievable laboratory MDL, and ideally 10 times the achievable laboratory MDL. Calibration curves should always include a standard concentration at the QL to ensure sensitivity. QLs are also known as practical quantitation limits (PQLs) and minimum levels (MLs).

- Frequently, QLs for specific samples must be adjusted for dilutions, changes to sample volume/size and extract/digestate volumes, percent solids, and cleanup procedures. These QLs are then referred to as sample quantitation limits (SQLs) or reporting limits (RLs). SQLs/RLs must be *less than* the project Action Limits for project quality objectives to be definitively met. Sample results that are reported to SQLs/RLs that are higher than the project Action Limits cannot be used to determine whether the Action Limit has been exceeded. Thus, environmental decision-making may be adversely affected by the failure to meet project QLs.

2.7.2.7 Completeness

The QAPP must address how completeness will be calculated. Determine quantitative measurement performance criteria for acceptable completeness for each matrix, analytical parameter, and concentration level. Also determine analyte-specific measurement performance criteria, if applicable. Identify which QA/QC activities will be performed to measure completeness.

Completeness is a measure of the amount of usable data collected using a measurement system. It is expressed as a percentage of the number of valid measurements that should have been collected. Separate values should be provided for the whole data set versus critical data (a subset of the whole data set). Since lack of data completeness may require resampling and additional costs, discuss how sufficient data will be guaranteed for critical sample locations.

The Measurement Performance Criteria Table shown in Figure 14 contains information for each medium/matrix, analytical parameter/method/ SOP, and concentration level. Figure 14 corresponds to Optional Worksheet #11 in the QAPP workbook.

Figure 14. Measurement Performance Criteria Table

Medium/Matrix	*Ground Water*
Analytical Parameter	*VOA*
Concentration Level	*Low*

Sampling Procedure	Analytical Method/SOP	Data Quality Indicators (DQIs)[1]	Measurement Performance Criteria	QC Sample and/or Activity Used to Assess Measurement Performance	QC Sample Assesses Error for Sampling (S), Analytical (A) or both (S&A)

[1]Data Quality Indicators (a.k.a. PARCC parameters, i.e., precision, accuracy/bias, sensitivity, data completeness, comparability)

After measurement performance criteria have been established, data generators and QA personnel can select sampling and analytical procedures/methods. They will select methods and procedures that have QC acceptance limits that support the achievement of established performance criteria. The determination of the analytical data validation criteria should be concurrent with the development of measurement performance criteria and the selection of sampling and analytical procedures/methods. Data users and QA personnel should select data validation criteria that support both the established project-specific measurement performance criteria and the analytical method/procedure QC acceptance limits. This will ensure that only data meeting project-required measurement performance criteria are used in decision-making.

3.0 MEASUREMENT AND DATA ACQUISITION ELEMENTS

This QAPP element group includes how project data will be collected, measured, and documented. Proper implementation of those activities/tasks will help to ensure that the resultant data are scientifically sound, of known and documented quality, and suitable for their intended use.

Quality control activities that will be performed during each phase of data collection/generation, from sampling to data reporting, are identified. QC acceptance limits are documented and the required corrective actions for nonconformances are described. It is important to remember that each phase of data collection/generation is interdependent and, therefore, quality must be factored into all project activities/tasks. The other two QAPP element groups, Assessment/Oversight and Data Validation and Usability, evaluate the activities/tasks described in this Measurement/Data Acquisition element group.

3.1 Sampling Tasks

The sampling sections of the QAPP include all components of the project-specific sampling system, including sampling process design and rationale, sampling procedures and requirements, as well as sample handling and custody requirements. **To simplify QAPP preparation, written SOPs should be included as attachments to the QAPP whenever possible.**

These sections of the QAPP should provide sufficient documentation to assure the reviewer that representative samples of the appropriate medium/matrix will be properly and consistently collected at the appropriate locations and that preventive and corrective action plans are in place prior to initiation of the sampling event. The terms “medium” and “matrix” are frequently used interchangeably. More accurately, however, medium refers to a substance (e.g., air, water, soil), whereas matrix refers to a specific type of medium (e.g., surface water, drinking water, etc.).

3.1.1 Sampling Process Design

This section of the QAPP describes the sampling system in terms of what media/matrices will be sampled, where the samples will be taken, the number of samples to be taken, and the sampling frequency. **Whether the QAPP describes an initial site investigation, a large-scale remedial investigation/feasibility study, a long-term treatment monitoring program, or a volunteer monitoring program, the rationale for sampling specific points or locations must be explained in the QAPP.**

3.1.1.1 Sampling Design Rationale

For each medium/matrix, provide detailed justification for the sampling design selected for the project, including background sample locations. Describe the logic used to determine sample locations, analytical parameters, and concentration levels, and the type, number, and frequency of field samples and field QC samples to be collected. Describe the following information pertaining to the sampling plan selection:

- If a grid system will be used to select random sampling locations, then describe the basis for selecting the size of the grid. If the grid system is to be used for long-term monitoring, or a high degree of accuracy is required, then the grid system should be surveyed by a certified land surveyor. Note that simple random sampling is used primarily when the variability of the medium is known to be relatively small (i.e., the medium is homogeneous).
- If biota will be sampled, describe the rationale for species and seasonal selection.
- If a watershed is being investigated, describe the rationale for sampling each medium and sample location.
- If surface water samples will be collected, describe the rationale for location selection.
- If field analytical measurements and/or screening techniques will be used to identify sample locations, provide decision trees that document the critical decision points of the selection process.
- If samples will be composited, provide the rationale and procedure for compositing.
- If a biased sampling approach will be used to select sampling locations, describe the rationale for choosing a nonstatistical approach.
- If biased/judgmental sampling will be performed, describe the criteria for selecting "hot spots."

Include additional site maps, charts, and plans to identify and document specific sample locations. Site maps must include the site borders, well boring, and test pit installations from previous investigations, as well as buildings, hills, water bodies, depressions, etc. and must identify all areas with known or suspected oil or chemical spills and/or toxic substance releases. The purpose of these maps is to allow unequivocal determination of sample locations.

Figure 15 shows headings for the Sampling Locations and Sampling and Analysis Methods/SOP Requirements Table. (Optional Worksheet #23 in the QAPP workbook.) Selected information from Sections 3.1.2, 3.2.1, and 3.2.2 of the QAPP is needed to complete this table.

Figure 15. Sampling Locations and Sampling and Analysis Methods/SOP Requirements Table

Sampling Location[1,2]	Location ID Number	Medium/ Matrix	Depth (units)	Analytical Parameter	Concentration Level	Number of Samples (identify field duplicates and replicates)	Sampling SOP	Analytical Method/ SOP	Sample Volume	Containers (number, size, and type)	Preservation Requirements (chemical, temperature, light protected)	Maximum Holding Time (preparation/ analysis)

[1]Indicate critical field sampling locations with "1".
[2]Indicate background sampling locations with "2".

3.1.2 Sampling Procedures and Requirements

This section of the QAPP describes how samples will be collected. The selected sampling procedures must be appropriate to ensure that representative samples are collected in a consistent manner by project personnel; that contamination is not introduced during collection; and that all required sample media/matrices, locations, and properly preserved volumes are collected to meet project objectives.

3.1.2.1 Sampling Procedures

All sampling procedures that will be used in the project must be documented in the QAPP to allow for review and approval. Standardized sampling procedures provide consistency between samplers; facilitate collection of accurate, precise, and representative samples; and help to ensure data comparability and usability. While it may be possible to comprehensively describe the sampling procedures for small projects within the text of the QAPP, the most efficient and cost- effective way to document project-specific sampling techniques is to include sampling SOPs as attachments to the QAPP.

SOPs can be written and formatted in accordance with the *Guidance for the Preparation of Standard Operating Procedures (SOPs) for Quality-Related Documents*, November 1995, EPA/600/R-96/027 (EPA QA/G-6). In addition to a detailed step-by-step description of the sampling procedure, all SOPs must specify acceptable limits of performance and required corrective actions.

Include SOPs for sampling each medium or matrix, for each analytical parameter, by each type of equipment and technique. The SOPs must detail the appropriate number, size, and type of sample containers to be used for collection of each field sample and field QC sample and the proper temperature, light, and chemical preservation procedure for those samples.

Include SOPs for any planned contingency actions that require additional and/or alternate procedures. For example, include procedures for sampling high-moisture-content soils/sediments when those matrices potentially contain peat.

Provide a detailed description, explanation, and SOP for the use of all new and/or innovative sampling techniques that will be employed during the project. Provide documentation of the procedures as well as performance data and criteria to support the use of new/innovative techniques.

Examples of sampling SOPs include, but are not limited to:

- Low Stress (low flow) Purging and Sampling Procedure for the Collection of Ground Water Samples from Monitoring Wells
- SOPs for Soil Sampling during Monitoring Well Installation
- Sampling SOPs for Surface and Subsurface Soils
- SOPs for the Collection of Sediments
- SOPs for the Collection of Surface Water Samples from Lakes, Ponds, and Streams
- SOPs for the Collection of Drinking Water from Residential Homes
- Sampling SOPs for Ambient Air, Stack Gases, and Soil Gas
- SOPs for Collection of Samples from Waste Storage Tanks and Waste Drums
- Sample Compositing SOPs
- Split Sampling SOPs
- Equipment Cleaning SOPs
- Equipment Decontamination SOPs
- Field Equipment Calibration SOPs
- Field Equipment Maintenance, Testing, and Inspection SOPs
- SOPs for Inspection and Acceptance Requirements for Supplies

Provide a Project Sampling SOP Reference Table that contains the information shown in Figure 16. Figure 16 corresponds to Optional Worksheet #13 in the QAPP workbook.

Figure 16. Project Sampling SOP Reference Table

Reference Number	Title, Revision Date, and/or Number	Originating Organization	Equipment Identification	Modified for Project Work Y or N	Comments

Note that all project sampling SOPs must be listed, including, but not limited to, sample collection, sample preservation, equipment cleaning and decontamination, equipment testing, inspection and maintenance, supply inspection and acceptance, and sample handling and custody SOPs.

3.1.2.2 Sampling SOP Modifications

If routine sampling SOPs are modified to meet project quality objectives, describe the modification(s) in this section of the QAPP and indicate, if used, that a modification occurred. Note the example heading on Figure 16.

3.1.2.3 Cleaning and Decontamination of Equipment/Sample Containers

This section of the QAPP details both the procedures for the initial cleaning of sampling equipment *and* subsequent decontamination procedures that will be followed during the sampling event. These procedures help to ensure that collected samples are representative of the sampling location by verifying that sampling equipment is clean and free of contaminants of concern, other target compounds, and/or interferences. Cleaning/decontamination procedures must cover all equipment that contacts a sample.

3.1.2.3.1 *Equipment Cleaning SOPs*

Include equipment cleaning SOPs as attachments to the QAPP. Also, list these SOPs on the sampling SOP table. Initial equipment cleaning should address:

- How equipment will be cleaned initially prior to field activities
- Frequency at which equipment will undergo full cleaning protocols
- Criteria for measuring cleanliness

If precleaned bottles are used, the QAPP should identify the vendor and describe where the certificates of cleanliness will be maintained.

3.1.2.3.2 *Equipment Decontamination SOPs*

Include equipment decontamination SOPs as attachments to the QAPP. Also, list these SOPs on the sampling SOP table. Decontamination procedures for each type of equipment should address:

- How equipment will be decontaminated in the field
- Frequency at which equipment will be decontaminated
- Criteria for measuring the effectiveness of the decontamination procedures
- Disposal of decontamination by-products, if applicable

Discuss or include a table identifying *all* the equipment that will come in contact with each sample for each medium/matrix. The following table provides an example.

Equipment	Matrices			
	Soil	Sediment	Groundwater	Surface Water
Split Spoon Sampler	X			
Eckman Dredge		X		
Submersible Pump			X	
Kemperer Tube				X

If applicable, discuss or include a table identifying equipment that will come into contact with each sample for each medium/matrix and for a specific analytical parameter. The following table provides an example.

Matrix: Soil Equipment	Parameter		
	VOA	Semivolatile	Metals
Encore Sampler	X		
Split Spoon Sampler		X	X
Stainless Steel Bowl		X	X
Plastic Scoop			X

3.1.2.4 Field Equipment Calibration

This section of the QAPP ensures that all field equipment, including tools, gauges, pumps, etc., is calibrated to ensure performance within specified limits and to ensure that corrective action measures are taken to fix problems prior to and during field operations. The information provided on the tables should demonstrate the ability of the equipment to collect representative samples and data during field operations. All field equipment other than analytical instrumentation must be listed, including but not limited to tools, gauges, and pumps. See Figure 17 for example headings of a Field Sampling Equipment Calibration Table. Include field equipment calibration procedures as an attachment to the QAPP. Calibration of field equipment should follow EPA procedures where appropriate. Figure 17 corresponds to Optional Worksheet #14 in the QAPP workbook.

Figure 17. Field Sampling Equipment Calibration Table

Equipment	Procedure	Frequency of Calibration	Acceptance Criteria	Corrective Action (CA)	Person Responsible for CA	SOP Reference*

*** Specify appropriate reference letter/number from the Project Sampling SOP Reference Table.**

3.1.2.5 Field Equipment Maintenance, Testing, and Inspection Requirements

This section of the QAPP describes the procedures and documentation activities that will be performed to ensure that field and sampling equipment are available and in working order when needed. Equipment maintenance logs must be kept and equipment must be checked prior to use. Describe the records that will be kept to document field equipment maintenance, testing, and inspection activities. Also, discuss the availability of spare parts and/or equipment to ensure that project schedules are met. Figure 18 shows example headings from a Field Equipment Maintenance, Testing, and Inspection Table, which corresponds to Optional Worksheet #15 in the QAPP workbook.

Figure 18. Field Equipment Maintenance, Testing, and Inspection Table

Sampling Equipment/ Instrument	Maintenance Activity	Testing Activity	Inspection Activity	Responsible Person	Frequency	Acceptance Criteria	Corrective Action	SOP Reference*

*** Specify appropriate reference letter/number from the Project Sampling SOP Reference Table.**

3.1.2.6 Inspection and Acceptance Requirements for Supplies/Sample Containers

This section of the QAPP documents the procedures and activities that will be performed to ensure that all sampling supplies and sample containers are free of contaminants of concern, other target compounds, and interferences.

Itemize the supplies and sample containers that will be used when performing field activities, including sampling activities. Identify all vendors for supplies and sample containers.

Describe the procedures that will be used to ensure that adequate supplies and sample containers are on hand and sample containers are traceable and clean. Discuss procedures for tracking, storing, and recording supplies and lot numbers for sample containers, as well as procedures for verifying container cleanliness, such as bottle blank analysis. Document the frequency of inspection activities, acceptance criteria, and corrective action procedures employed to prevent the use of unacceptable

supplies and/or sample containers. Identify the personnel responsible, by job function and organizational affiliation, for checking supplies, sample containers, and sample container certificates of cleanliness, and the personnel responsible for implementing corrective actions. If this information is contained in an SOP, then cite the SOP reference number and include the SOP as an attachment to the QAPP.

3.1.3 Sample Handling, Tracking, and Custody Requirements

3.1.3.1 Sample Collection Documentation

This section of the QAPP describes field documentation procedures that will be followed for the project. Field analytical and fixed laboratory documentation procedures are discussed in Section 3.5.1, in conjunction with data management and project records. Proper field sampling documentation, and field analytical and laboratory documentation, help to ensure sample authenticity (i.e., the sample identity is correct) and data integrity.

3.1.3.1.1 *Field Notes*

To provide a permanent record of field activities and possible introduction of sampling error, observations made and measurements taken in the field must be recorded. Typically, field data are recorded in field logbooks or on field data collection forms.

The following information should be included in the field logbooks/field data collection forms:

- Site name and location
- Sample project identification number
- Names, job functions, and organizational affiliations of personnel on-site
- Dates (month/day/year) and times (military) of all entries made in logbooks/forms, and user signatures
- Descriptions of all site activities, including site entry and exit times
- Site location by longitude and latitude centroid, if known
- Weather conditions, including temperature and relative humidity
- Site observations
- Identification and description of sample morphology and collection locations
- Sample collection information, including dates (month/day/year) and times (military) of sample collections, sample collection methods and devices, station location numbers, sample collection depths/heights, sample preservation information, sample pH (if applicable), analysis requested (analytical parameters), etc., as well as chain-of-custody information such as sample location identification numbers cross-referenced to field sample numbers

- Laboratories receiving samples and shipping information, such as carrier, shipment time, number of sample containers shipped, and analyses
- Contractor and subcontractor information (address, names of personnel, job functions, organizational affiliations, and contract number, contract name, and work assignment number)
- Records of photographs taken
- Site sketches and diagrams made on-site

Describe the field information that will be recorded for each medium/matrix and each type of sampling procedure, since field information is medium/matrix and procedure dependent. For example, documentation of monitoring well sample collection should provide documented information that includes screen interval, pump intake, purge rate, purge volume, temperature, relative humidity, specific conductance, pH, redox potential, dissolved oxygen, and turbidity. For a soil boring, the documented field information should include drilling method, borehole diameter, ground elevation, water level, and soil descriptors like color, odor, and grain size.

If field data collection forms will be used, include examples of the forms as figures in this section of the QAPP. Alternatively, include the examples as attachments to the QAPP and reference the appropriate attachment.

If field notebooks will be used, then include the requirements for the notebooks in this section. Bound notebooks with water-resistant, sequentially numbered pages and indelible ink entries should be required.

Regardless of the means of recording sampling information, copies of field data records should be included with the associated Data Validation Reports to facilitate the identification of sampling error.

3.1.3.1.2 *Field Documentation Management System*

Describe the field documentation tracking and management system as a part of the overall project data tracking and management system, which is described in Section 3.5.1. The title of each notebook should indicate its function, and each notebook used for a specific site or project should be referenced to all the other project notebooks, including the Project Manager's daily log. Also, each notebook should be tracked and archived with other project records in accordance with the project data management system.

3.1.3.2 Sample Handling and Tracking System

This section of the QAPP documents the procedures that will be followed to identify and track samples collected in the field, samples analyzed in the field, and samples delivered or shipped to a

fixed laboratory for analysis, as well as sample transfer throughout the laboratory. If samples are shipped to a fixed laboratory(s), then the laboratory's sample handling and tracking system should be described in this section. Proper sample tracking systems support the chain-of-custody procedures, which, in turn, help to ensure sample authenticity and data defensibility.

- ***Define the term "sample" or reference the regulatory definition.*** Since the definition of sample is program-dependent, ensure the correct usage of the term. If a soil sample is operationally defined in the field by mesh size, then this should be noted. Also, if a laboratory subsamples a field sample based on certain criteria (e.g., mesh size), then those activities and definitions should be documented in this section of the QAPP.

- ***Describe the sample numbering system for field sample collection and provide an example.*** If applicable, the numbering system should follow specific programmatic requirements that apply to the project. Use a systematic approach for numbering samples so that each sampling location, medium/matrix type, sample depth or height, and date/time of collection can be uniquely identified and cross-referenced to the programmatic sample number, if applicable.

- ***Describe the laboratory sample tracking procedures.*** If laboratory identification numbers will be used to track samples internally, then the laboratory procedure must describe how these laboratory identification numbers will be cross-referenced with the sample number assigned in the field.

- ***Describe temperature and preservation (including light protection) procedures that***

  — maintain sample integrity in the field prior to and during shipment to the laboratory.
  — maintain sample integrity immediately upon receipt by the fixed laboratory or mobile field laboratory.

- ***Describe sample storage procedures used by the fixed laboratory or mobile field laboratory.***

3.1.3.2.1 *Sample Container, Volume, and Preservation Table*

Document all required sample volumes, container types, numbers of containers, and preservation procedures (temperature, light, chemical) in a table. Provide the information for each analytical parameter, matrix, and concentration level in a table.

Define how samples will be batched or grouped to be sent to the laboratory. It is recommended that samples be grouped in Sample Delivery Groups (SDGs). An SDG is defined as a group of 20 or

fewer field samples within a project, received by a laboratory over a period of up to 14 calendar days. Performance evaluation samples (PESs) and other field QC samples (e.g., equipment blanks, VOA trip blanks) are counted as field samples in the 20-sample SDG total.

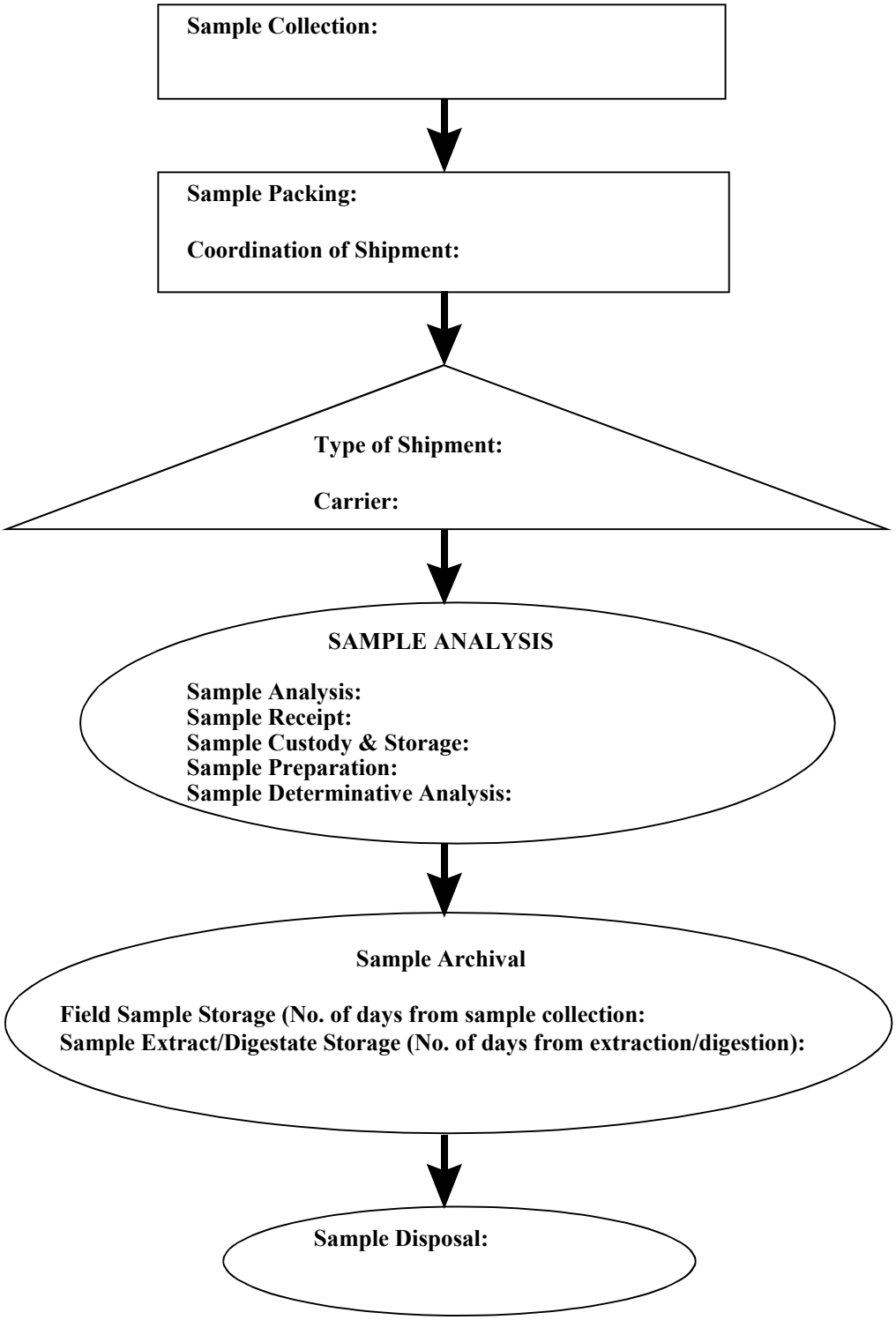
Describe how samples will be delivered or shipped to the laboratory. Include the name of the carrier service, if applicable. Samples should be transported directly to the laboratory within 24 hours of sample collection, or be shipped by an overnight delivery service (with coolers under custody seal) within 24 hours of sample collection. A major exception to this requirement is when published analytical holding times are less than 24 hours from sample collection. If alternate shipment schedules will be used, describe those alternate timeframes and provide rationale for their use. Shipment papers, including bills of lading and airbills, must be retained by the laboratory with chain-of-custody records.

Include provisions for packaging, marking/labeling, and shipping samples in compliance with the most recent U.S. Department of Transportation (DOT) regulations for shipping hazardous and nonhazardous materials. Air carriers that transport hazardous materials require compliance with the current edition of the International Air Transport Association (IATA) Dangerous Goods Regulations, which applies to shipment and transportation of hazardous materials by air carriers. Following IATA regulations will also ensure compliance with U.S. DOT regulations. Include examples of all sample shipment forms to be used (these may be the same as the chain-of-custody forms, which are discussed in Section 3.1.3.3 of this UFP-QAPP Manual.)

3.1.3.2.2 *Sample Handling Flow Diagram*

Provide a flowchart that diagrams the flow of samples from the time of collection to laboratory delivery to final sample disposal (see Figure 19 for an example flow diagram). Indicate the personnel, and their organizational affiliations, who are primarily responsible for ensuring proper sample handling, custody, storage, and disposal. Specify the length of time that samples, digestates and/or extracts, and biological collections will be retained by the laboratory prior to disposal. Figure 19 corresponds with Optional Worksheet #16 in the QAPP workbook.

Figure 19. Sample Handling Flow Diagram



3.1.3.2.3 *Sample Container Label (Sample Tag)*

Specify the required sample label information in this section and include an example of a sample container label. Sample containers should be labeled, using indelible ink, with the following minimum information:

- Site name and location
- Sample project identification number
- Sample collection location and depth/height
- Collection date (month/day/year) and time (military)
- Sample collection method (composite or grab) and device
- Sample preservation method (chemical or physical, e.g., ice; indicate if sample must be light protected)
- Sample pH, if applicable
- Analysis requested (analytical parameter)
- Sampler's signature

Describe how the information on the label will be preserved, such as covering the label with clear tape to minimize water damage during transit.

3.1.3.3 Sample Custody

A sample is in "custody" if it is in the actual physical possession of authorized personnel or in a secured area that is restricted to authorized personnel. For some projects, an evidentiary paper trail documenting sample custody is required to meet project quality objectives. Since it is often difficult to predict what samples and/or projects will require proof of custody after the fact, all data collection events should employ standard chain-of-custody procedures and documentation to ensure data authenticity and defensibility.

This section of the QAPP describes the procedures that will be used to maintain sample custody and integrity and to document implementation of proper chain-of-custody procedures. The evidentiary trail from sample collection through data generation and archival is maintained using sample custody procedures and documented by complete chain-of-custody records, including chain-of-custody forms, traffic reports, sample tags/labels, cooler custody seals, sample custody seals, laboratory sample receipt forms, laboratory sample transfer forms, etc. Note that only through complete documentation can the end user prove that the individual sample results are reflective of a particular sample (collected at a specific site location on a unique date and time) and that the sample was handled as prescribed. Chain-of-custody procedures ensure accountability for the location and integrity of the sample at all times. Refer to the EPA policy document, *National Enforcement*

Investigations Center (NEIC) Policies and Procedures (EPA-330/9-78-001-R, May 1978), Rev. December 1981, for information regarding chain-of-custody procedures.

Include the **field sampling team's procedures** for maintaining and documenting sample custody from the time samples are collected in the field through packaging, shipment, and delivery to the laboratory. Field sampling documents that describe chain-of-custody procedures, including SOPs, should be included as an attachment to the QAPP. Include the **laboratory's procedures** for maintaining and documenting sample custody from the time the samples are received at the laboratory through archival and disposal. Laboratory documents that describe the chain-of-custody procedures should be included as an attachment to the QAPP.

Chain-of-Custody Documentation. Provide examples of all chain-of-custody documentation, including chain-of-custody forms, traffic reports, sample tags/labels, custody seals, laboratory sample receipt forms, laboratory sample transfer forms, etc., that will be used during the project.

Sample Handling, Tracking, and Custody SOPs. Include as attachments to the QAPP all sample handling, tracking, and custody procedures that ensure that sample integrity/custody is maintained during sample collection, packaging, handling, and shipping, through laboratory sample receipt, archival, and disposal. List sampling chain-of-custody SOPs. List COC SOPs associated with field or fixed laboratory analysis. Refer to Optional Worksheets #17 and #20 in the QAPP workbook for example table headings.

Examples of sample handling, tracking, and custody SOPs include, but are not limited to:

- Field Documentation SOPs and Records Management SOPs
- Sample Custody/Sample Security SOPs (field)
- Sample Handling and Tracking SOPs (field)
- Sample Packaging and Shipping SOPs (field)
- Sample Receipt and Storage SOPs (laboratory)
- Sample Custody/Sample Security SOPs (laboratory)
- Sample Tracking SOPs (laboratory)
- Sample Disposal or Archival SOPs (laboratory)

3.2 Analysis Tasks

The following sections of the QAPP include all components of the project-specific analytical measurement system, including field and fixed laboratory analytical methods and SOPs; method- and laboratory-specific QC measurements, acceptance criteria, and corrective actions; calibration procedures; and instrument/equipment/supply maintenance, testing, and inspection requirements.

Field analytical tasks are those analytical activities that are not performed in a fixed laboratory. Field analysis includes both semiquantitative/semiqualitative field screening techniques and definitive full-protocol analytical methods. Definitive data may be generated for field parameters, including specific conductance, temperature, DO, pH, turbidity, and ORP/Eh using field instrumentation. Definitive inorganic and organic data may be generated in a mobile field laboratory equipped with a GC, GC/MS, ICP, etc.

These sections of the QAPP should provide sufficient documentation to assure the reviewer that accurate, precise, and usable data will be generated and that preventive and corrective action plans are in place prior to the initiation of the sampling event.

All contracted and/or subcontracted field analytical and fixed laboratory services must be in place for the final QAPP to be approved.

Where regulatory and/or programmatic requirements specify that a laboratory be certified (e.g., EPA water supply program), documentation of the laboratory certification must be included as an attachment to the QAPP.

3.2.1 Field Analytical Method Requirements

This section of the QAPP describes the analytical techniques that will be used in the field or by an on-site mobile laboratory to generate screening data as well as definitive data for the project. It documents the field analytical methods and SOPs that will be used to meet measurement performance criteria and achieve project-required quantitation limits for the contaminants of concern and other compounds at the target concentration levels and in the specific media/matrices. Note the difference between methods and analytical SOPs: methods describe preparatory and analytical/determinative techniques used in target analyte identification and quantitation, while analytical SOPs document how a particular laboratory will perform a specific analytical method.

3.2.1.1 <u>Field Analytical Methods and SOPs</u>

All field analytical methods and procedures that will be used in the project must be documented in the QAPP to allow for review and approval. Differentiate between field screening procedures and field analytical procedures used to generate definitive data. While it may be possible to describe simple field analytical procedures within the text of the QAPP, the most efficient and cost-effective way to document project-specific measurement procedures is to include analytical methods and SOPs as attachments to the QAPP. Include methods/SOPs for each analytical parameter, medium/matrix, and concentration level that will be investigated. All methods/SOPs must contain

the maximum allowable holding time from sample collection to sample preparation and/or analysis (as appropriate).

If definitive data will be generated using a mobile on-site laboratory, then the organization operating that mobile laboratory must provide the equivalent of a Laboratory QA Plan/UFP-QAPP Manual, to be included as an attachment to the QAPP if definitive data are generated. This document may not be necessary if only field screening data are being generated. However, the SOPs for the screening methods must be referenced in the QAPP and be available to the personnel performing the screening and upon request.

Analytical methods should be written and formatted in accordance with the Environmental Monitoring Management Council (EMMC) Method Format. Analytical methods must specify appropriate QC checks and samples with explicit concentration and frequency requirements for preparation and analysis, QC acceptance limits, and required corrective actions for each step of the method.

Analytical SOPs should be written and formatted in accordance with the *Guidance for the Preparation of Standard Operating Procedures (SOPs) for Quality-Related Documents*, November 1995, EPA/600/R-96/027 (EPA QA/G-6). In addition to a detailed step-by-step description of the procedure, all SOPs must specify appropriate QC checks and samples with explicit concentration and frequency requirements for preparation and analysis, QC acceptance limits, and required corrective actions for each step of the procedure.

Include analytical methods and SOPs for any planned contingency analytical work that may be required.

Provide a detailed description, explanation, and SOP for the use of all new and/or innovative analytical techniques that will be employed during the project. Provide documentation of the procedures as well as method performance data and criteria to support the use of new/innovative techniques.

Examples of field analytical methods and SOPs include, but are not limited to:

- EPA Standard Methods
- Field Analytical SOPs
- Sample Receipt and Storage SOPs
- Sample Tracking SOPs
- Sample Preparation SOPs
- Glassware Cleaning SOPs
- Calibration SOPs

- Maintenance, Testing, and Inspection Activities SOPs
- Analytical Standards Preparation and Traceability SOPs
- Data Reduction Procedures
- Documentation Policies/Procedures
- Data Verification Procedures
- Data Management Procedures
- Sample and Sample Extract/Digestate Disposal SOPs

Provide a Field Analytical Method/SOP Reference Table that contains the information provided in the headings in Figure 20. Figure 20 corresponds to Optional Worksheet #17 in the QAPP workbook.

Figure 20. Field Analytical Method/SOP Reference Table

Reference Number	Title, Revision Date, and/or Number	Definitive or Screening Data	Originating Organization	Analytical Parameter	Instrument	Organization Performing Field Analysis	Modified for Project Work Y or N

3.2.1.2 Field Analytical Method/SOP Modifications

If full-protocol methods or other published methods and/or standard SOPs are modified to meet project quality objectives, then describe those modification(s) in this section of the QAPP. For example, a field screening analytical SOP for analyzing PCBs in soil requires that 1 gram of soil be extracted. If previously collected site data showed high levels of PCB contamination (i.e., above the calibrated measurement range), then the data generators may choose to extract a smaller volume of sample. This would constitute a modification to the SOP.

3.2.1.3 Field Analytical Instrument Calibration

To ensure that the analytical methods and the selected instrumentation meet the project requirements for selective, sensitive, accurate, and precise detection and quantitation of the analytes of interest, it is necessary to completely describe the calibration procedures for each field analytical instrument. This section of the QAPP demonstrates the ability of the field analytical technique to accurately and precisely identify and quantitate the contaminants of concern and other target compounds at the required quantitation limits and within the required measurement ranges.

Provide a Field Analytical Instrument Calibration Table that contains the information shown in Figure 21 and lists all field analytical instrumentation, including but not limited to screening

instruments, XRF, total organic vapor analyzers (PID or FID), portable GCs, and immunoassay kits. Figure 21 corresponds to Optional Worksheet #18 in the QAPP worksheet.

All instruments must be calibrated according to a schedule specified by the method and instrument manual or SOPs.

Figure 21. Field Analytical Instrument Calibration Table

Instrument	Activity	Frequency of Calibration	Acceptance Criteria	Corrective Action (CA)	Person Responsible for CA	Method/SOP Reference*

*** Specify appropriate reference letter/number from Field Analytical Method/SOP Reference Table.**

Calibration procedures may be documented separately in this section of the QAPP or included in the appropriate field analytical SOPs as attachments to the QAPP. In either case, the following items, where appropriate, must be addressed for each analytical procedure:

- Frequency of initial and continuing calibrations.
- Number of calibration points, calibration levels for multipoint curves, and calibration standards at the required quantitation limit concentration for each contaminant of concern and other target compounds.
- Linearity calculation techniques.
- Acceptance criteria for calibrations.
- Calibration level for calibration verification standards. In order to assess instrument drift, a calibration verification standard should be run periodically during the analytical sequence and at the end of the analytical sequence.
- Corrective actions for nonconformances.
- Calibration/Standards Documentation: Describe what documentation will be generated for calibrations and standards for each instrument. Note that a plot for each regression curve must be provided for all nonlinear curves that will be used to quantitate field samples.
- Standards Traceability: Describe the procedures to be used to ensure standard traceability. Standards must be traceable to a verifiable source such as a NIST standard. Standards may be purchased as ampulated mixtures with certificates of analysis; however, it is the laboratory's responsibility to ensure the accuracy of the standard solutions.
- Second Source Verification: Describe the use of second source verification standards. Even certified standards may change over time or not meet vendors' specifications. A relatively inexpensive way to verify the analytes and concentration of a standard is to analyze a standard containing the same analytes from another vendor. By applying routine comparability criteria, greater assurance is gained in the identification and quantitation of

target analytes in an analytical sample. The data from the two standards can be compared using previously established comparability criteria to assess accuracy.

3.2.1.4 Field Analytical Instrument/Equipment Maintenance, Testing, and Inspection Requirements

This section of the QAPP describes the procedures and documentation activities that will be performed to ensure that all field analytical instrumentation and equipment are available and in working order when needed.

Instrument/equipment maintenance logs must be kept, and instrumentation and equipment must be checked prior to use. Describe the records that will be kept to document field analytical equipment/instrumentation maintenance, testing, and inspection activities.

Discuss the availability of spare parts or spare instruments to ensure that project schedules are met. Discuss how instruments are controlled in the field and during storage, instrument security, and log-in/log-out procedures to ensure instrument availability.

Provide a table that contains the information shown in the headings in Figure 22. Figure 22 corresponds to Optional Worksheet #19 in the QAPP workbook.

Figure 22. Field Analytical Instrument/Equipment Maintenance, Testing, and Inspection Table

Instrument	Maintenance Activity	Testing Activity	Inspection Activity	Frequency	Acceptance Criteria	Corrective Action	Responsible Person	Method/SOP Reference*

*** Specify appropriate reference letter/number from Field Analytical Method/SOP Reference Table.**

3.2.1.5 Field Analytical Inspection and Acceptance Requirements for Supplies

This section of the QAPP documents the procedures and activities that will be performed to ensure that all supplies used in field analytical work will be available when needed and will be free of contaminants of concern, other target compounds, and interferences.

Itemize the supplies that will be used when performing field analytical work. Identify all vendors for supplies and reagents.

Describe the procedures that will be used to ensure supply cleanliness and reagent purity. Discuss procedures for recording reagent lot numbers and procedures for measuring supply cleanliness.

Document corrective action procedures employed to prevent the use of unacceptable supplies. Identify the person(s) responsible for checking supplies and implementing corrective actions. If this information is contained in an SOP, then cite the SOP reference.

3.2.2 Fixed Laboratory Analytical Method Requirements

This section of the QAPP describes the analytical techniques that will be used by the fixed laboratory to generate screening as well as definitive data for a project. It documents the fixed laboratory analytical methods and SOPs that will be used to meet measurement performance criteria and achieve project-required quantitation limits for the contaminants of concern and other target compounds at the concentration levels and in the specific media/matrices as identified in Section 2.6.1. Note the difference between methods and analytical SOPs: methods describe preparatory and analytical/determinative techniques used in target analyte identification and quantitation, while analytical SOPs document how a particular laboratory will perform a specific analytical method.

3.2.2.1 Fixed Laboratory Analytical Methods and SOPs

Fixed Laboratory Analytical Methods and SOPs – All fixed laboratory analytical methods and procedures that will be used in the project must be included in the QAPP to allow for review and approval. While it may be possible to describe simple fixed laboratory analytical procedures within the text of the QAPP, the most efficient and cost-effective way to document project-specific measurement procedures is to include analytical methods and SOPs as attachments to the QAPP. Include methods/SOPs for each analytical parameter, medium/matrix, and concentration level that will be investigated. All methods/SOPs must contain the maximum allowable holding time from sample collection to sample preparation and/or analysis (as appropriate).

If the analytical procedures are documented in the fixed laboratory's QA plan or manual, then it may be easiest to include the relevant sections in the project QAPP or reference the appropriate sections of those documents in the project QAPP. This would preclude including separate analytical SOPs (assuming that those relevant sections of the fixed laboratory's QA plan/manual contain all of the required information). Laboratory QA plans or manuals must be included for each laboratory retained to provide analytical services.

Analytical methods should be written and formatted in accordance with the EMMC guidance. Analytical methods must specify appropriate QC checks and samples with explicit concentration and frequency requirements for preparation and analysis, QC acceptance limits, and required corrective actions for each step of the method.

Analytical SOPs should be written and formatted in accordance with *Guidance for the Preparation of Standard Operating Procedures (SOPs) for Quality-Related Documents*, November 1995,

EPA/600/R-96/027 (EPA QA/G-6). In addition to a detailed step-by-step description of the analytical procedure, all SOPs must specify appropriate QC checks and samples with explicit concentration and frequency requirements for preparation and analysis, QC acceptance limits, and required corrective actions for each step of the method.

Include analytical methods and SOPs for any planned contingency analytical work that may be required.

Provide a detailed description, explanation, and SOP for the use of all new and/or innovative analytical techniques that will be employed during the project. Provide documentation of the procedures as well as method performance data and criteria to support the use of new/innovative techniques.

Examples of fixed laboratory methods and SOPs include, but are not limited to:

- EPA Standard Methods
- Fixed Laboratory Analytical SOPs
- Sample Receipt and Storage SOPs
- Sample Tracking SOPs
- Sample Preparation SOPs
- Glassware Cleaning SOPs
- Calibration SOPs
- Maintenance, Testing, and Inspection Activities SOPs
- Analytical Standards Preparation and Traceability SOPs
- Data Reduction Procedures
- Documentation Policies/Procedures
- Data Verification Procedures
- Data Management Procedures
- Sample and Sample Extract/Digestate Disposal SOPs

Provide a Fixed Laboratory Analytical Method/SOP Reference Table that contains the information shown in the headings in Figure 23. Figure 23 corresponds to Optional Worksheet #20 in the QAPP workbook.

Figure 23. Fixed Laboratory Analytical Method/SOP Reference Table

Reference Number	Fixed Laboratory Performing Analysis	Title, Revision Date and/or Number	Definitive or Screening Data	Analytical Parameter	Instrument	Modified for Project Work Y or N

3.2.2.2 Fixed Laboratory Analytical Method/SOP Modifications

If standard EPA methods or other published methods and/or SOPs are modified to meet project quality objectives, then describe those modification(s) in this section. For example, the EPA CLP Low/Medium Concentration VOA Method in the Statement of Work for Organic Analysis OLM03.2 specifies a target compound list of 33 volatile organic compounds. The project planning team may choose to add an additional compound (e.g., dioxane) to the target compound list because it is a contaminant of concern at the site. This would constitute a modification to the standard EPA method.

3.2.2.3 Fixed Laboratory Instrument Calibration

To ensure that the analytical methods and the selected instrumentation meet the project requirements for selective, sensitive, accurate, and precise detection and quantitation of the analytes of interest, it is necessary to completely describe the calibration procedures for each fixed laboratory analytical instrument. This section of the QAPP demonstrates the ability of the fixed laboratory analytical technique to accurately and precisely identify and quantitate the contaminants of concern and other target compounds at the required quantitation limits and within the required measurement ranges.

Provide a Fixed Laboratory Instrument Maintenance and Calibration Table that lists all fixed laboratory analytical instrumentation and contains the information shown in Figure 24. Figure 24 corresponds to Optional Worksheet #21 in the QAPP workbook.

Figure 24. Fixed Laboratory Instrument Maintenance and Calibration Table

Instrument	Activity	List Maintenance, Testing, and Inspection Activities	Frequency of Calibration	Acceptance Criteria	Corrective Action (CA)	Person Responsible for CA	Method/SOP Reference*

*** Specify appropriate reference letter/number from Fixed Laboratory Analytical Method/SOP Reference Table.**

Calibration procedures may be documented separately in this section of the QAPP or included in the appropriate fixed laboratory analytical SOPs as attachments to the QAPP. In either case, the items listed in Section 3.2.1.3 must be addressed for each analytical procedure.

3.2.2.4 Fixed Laboratory Instrument/Equipment Maintenance, Testing, and Inspection Requirements

This section of the QAPP describes the procedures and documentation activities that will be performed to ensure that all fixed laboratory instrumentation and equipment are available and in working order when needed.

Equipment maintenance logs must be kept and equipment must be checked prior to use. Describe the records that will be kept to document fixed laboratory instrumentation maintenance, testing, and inspection activities.

Discuss the availability of spare parts or spare instruments to ensure that project schedules are met. Discuss how instruments are controlled, instrument security, and log-in/log-out procedures to ensure instrument availability.

List all instrument maintenance, testing, and inspection activities.

3.2.2.5 Fixed Laboratory Inspection and Acceptance Requirements for Supplies

This section of the QAPP documents the procedures and activities that will be performed to ensure that all supplies used in fixed laboratory work will be available when needed and will be free of contaminants of concern, other target compounds, and interferences.

Itemize the supplies that will be used when performing fixed laboratory work. Identify all vendors for supplies and reagents.

Describe the procedures that will be used to ensure supply cleanliness and reagent purity. Discuss procedures for recording reagent lot numbers and procedures for measuring supply cleanliness. Document corrective action procedures employed to prevent the use of unacceptable supplies. Identify the person(s) responsible for checking supplies and implementing corrective actions. If this information is contained in an SOP, cite the SOP reference. Alternatively, the required information may be presented in a table.

3.3 Quality Control Tasks

3.3.1 Quality Control Requirements

Quality control (QC) is the set of activities that are performed for the purposes of monitoring, measuring, and controlling the performance of a measurement process. QC activities are designed to measure the data quality indicators that are used to evaluate the different components of the measurement system, including sampling and analysis. Without sufficient and appropriate QC activities, an evaluation of planned projects may not be possible. In addition, without adequate planning, project-required activities may not be performed properly or may not be performed at required frequencies. It is necessary that a properly prepared QAPP explicitly detail what field and laboratory activities are to be conducted to meet project quality goals. It is equally important that all project personnel know and understand these activities.

Tables 4 and 5 (Section 3.3.1.2) note some of the most common QC activities that are to be incorporated into data collection activities. Those activities that commonly originate in the field are listed in Table 3. Table 4 contains activities that are usually initiated in the laboratory setting. These activities are also somewhat complementary to each other. For example, a single field blank successfully carried through an analytical process can show that the analytical process is free of significant contamination. For many purposes this may be adequate. However, if this single field blank were to show significant contamination, it would not be possible to ascertain the source of the contamination (i.e., whether it occurred in the field or the lab). Knowing the source would be invaluable in troubleshooting and correcting the cause. Because of these concerns, a typical project may include several different types of blanks, all originating at a different stage of the analytical scheme.

Although Tables 4 and 5 contain the most frequently run QC checks, not all checks are applicable to a given analytical procedure. For example, there has never been a good way to perform a spiked analysis for parameters like BOD. Likewise, physical or microbiological testing will often require different types of QC checks than chemical testing. Radiochemical testing will require different procedures than GC/MS for volatile organics. For these reasons, it is not possible to create a list of mandatory QC practices that will apply to all cases. Deciding the most appropriate QC checks is a key part of project planning and frequently requires some professional judgment. Many analytical methods (but not all) will also have very specific QC practices written into the method itself, which must also be followed.

The QAPP must clearly note which project personnel are expected to perform the activities. In addition, the QAPP must contain the following:

- An explicit description of the QC practice to be performed
- A required frequency at which it must be performed
- A description, usually in mathematical terms, of what constitutes acceptable performance for the QC check
- Indicated corrective actions to be taken if the QC check fails these criteria
- A description of how the QC data and results are to be documented and reported to the data user

Many times a tabular format is the most efficient way to present this type of information.

The results of QC checks are also a key factor in data validation and assessment. One of the most critical aspects of validation and assessment will be whether project-specific QC goals have been met. Data that meet project goals for quality can be reasonably expected to provide a sound basis for decision-making. On the other hand, failed QC checks often indicate large uncertainty associated with a data set and infer a corresponding large uncertainty in decisions based on such data.

3.3.1.1 Sampling Quality Control

This section of the QAPP identifies the QC procedures, checks, and samples, and their respective acceptance limits, that will be used during the project to monitor the quality of various aspects of the sampling event(s). Required analysis frequency, acceptance limits, and corrective actions are also documented in this section of the QAPP.

Table 3 provides a list of recommended field QC activities. However, the actual types and frequencies are determined in advance, during planning, based on the project-specific needs.

Field sampling QC tables should contain the information shown in Figure 25. Figure 25 corresponds to Optional Worksheet #22a in the QAPP workbook.

If method/SOP QC acceptance limits exceed the project-specific measurement performance criteria, then the data obtained may be unusable in making project decisions.

Table 3. Recommended Types of Field QC Samples and Frequency

Field QC	Data Quality Indicators[1]	Recommended Frequency[2]
Chemical		
Equipment Blank (rinsate blank)	Contamination (Accuracy/Bias)	Minimum 5% per parameter/per matrix/per sampling procedure/per sampling team
Bottle Blank (non-VOA)	Contamination (Accuracy/Bias)	Minimum 1 per lot # of bottles
VOA Trip Blank	Contamination (Accuracy/Bias)	Minimum 1 per shipment cooler
Cooler Temperature Blank (VOA only)	Preservation (Accuracy/Bias)	Minimum 1 per shipment cooler
Performance Evaluation Sample (PES)[3]	Accuracy/Bias	Minimum 1 per SDG/per parameter/per matrix/per concentration level
Field Duplicates[4] -Collocated Samples -Duplicate Subsamples	Precision	Minimum 5% per parameter/per matrix/per sampling procedure/per sampling team
Field Splits[5]	Interlaboratory Comparability	As per method and based on DQOs

Table 3. Recommended Types of Field QC Samples and Frequency (Continued)

Field QC	Data Quality Indicators[1]	Recommended Frequency[2]
Biological		
Biological QC Checks (Biological Specimen Samples)	Reproducibility, etc.	As per method and based on DQOs

[1]See Tables 4 and 5 for additional DQI information.
[2]The QAPP should indicate any deviations from recommended frequencies and provide justification.
[3]Performance evaluation samples, also known as double-blind samples, have been arbitrarily included under field QC samples. They primarily measure analytical error, since their composition is unknown to the laboratory and they originate outside of the laboratory.
[4]Field duplicates are two samples taken from and representative of the same population. Field duplicates are carried through all steps of the sampling and analytical procedures in an identical manner and provide overall precision information for the data collection event. Field duplicates can be subdivided into two categories: collocated samples and duplicate subsamples.

-Collocated samples are two samples collected next to each other in the same vertical position. They are the result of two separate sample collections at the same sample location. Collocated samples include ambient air monitoring samples, composite water samples, surface water grab samples, side-by-side sample corers, etc.

-Duplicate subsamples are subsamples of one sample collection at one sampling location. For example, duplicate subsamples are sometimes taken from soil borings or sediment cores.

[5]Split samples are two or more subsamples taken from a field sample and analyzed by different laboratories to assess interlaboratory comparability. Field samples are homogenized to correct for sample inhomogeneity that would adversely affect split sample data comparability prior to splitting. Split samples should be as identical as possible.

Figure 25. Field Sampling QC Table

Sampling SOP	
Medium/Matrix	
Analytical Parameter	
Concentration Level	
Analytical Method/ SOP Reference	
Sampler's Name	
Field Sampling Organization	
No. of Sample Locations	

Field QC:	Frequency/Number	Method/SOP QC Acceptance Limits	Corrective Action (CA)	Person(s) Responsible for CA	Data Quality Indicator (DQI)	Measurement Performance Criteria

If analytical parameters have multiple analytes, provide a Field Sampling SOP Precision and Accuracy Table that contains the information shown in Figure 26. List the field precision and accuracy/bias (in terms of contamination) expected for each analyte when using the specified sampling (and analytical) technique. Figure 26 corresponds to Optional Worksheet #22b in the QAPP workbook.

Figure 26. Field Sampling SOP Precision and Accuracy Table

Sampling SOP:
Analytical Method/SOP:

Analyte	Field Precision	Field Accuracy/Bias (Contamination)

3.3.1.2 Analytical Quality Control

This section of the QAPP identifies the QC procedures, checks, and samples, and their respective acceptance limits, that will be used during the project to monitor the quality of various preparatory and analytical steps. Many methods generally provide QC acceptance limits for most of the QC checks and samples required by those methods. Certain methods require that laboratories generate their own specific QC acceptance limits for some of the QC checks and samples required by those methods. These method- and laboratory-specific limits, however, may not be "tight" enough to support the project quality objectives. In other words, QC sample or check results may meet method/SOP QC acceptance limits but fail to meet the project measurement performance criteria as defined and documented in Section 2.7.2. Therefore, it is important to select methods having QC acceptance limits that support the collection of usable project data. Subsequently, it is critical to choose a laboratory that is capable of meeting the project-required QC acceptance limits. Again, method- and laboratory-specific QC acceptance limits, project measurement performance criteria, and project validation criteria must be complementary for project objectives to be achieved.

For some projects, the selected method may not have sufficient QC checks and samples built into the method. In these cases, the Project Team will need to specify what additional QC checks and samples must be analyzed by the laboratory. The laboratory should document additional project-required QC in its analytical SOPs, along with the required frequency acceptance criteria and corrective actions for those QC checks and samples. Table 4 lists types of field analytical and fixed laboratory QC checks, samples, and procedures.

Different types of QC checks and samples provide data that can be used to isolate different sources of error throughout the measurement system, including contamination, poor precision, poor

accuracy/bias, and poor sensitivity. Table 5 summarizes the information derived from different sampling, transportation, and laboratory QC checks and samples. Note that this list does not include all possible QC checks and samples that are available to the user. Also note that analytical methods may define the purpose of specific QC samples differently (e.g., dioxin methodologies), and therefore it is necessary to adhere to the QC definitions of the specific methods employed.

Table 4. Types of Field Analytical and Fixed Laboratory QC Checks/Samples and Recommended Frequency

Analytical QC	Data Quality Indicators[1]	Recommended Frequency[2]
Chemical		
Method Blank	Accuracy/Bias (Contamination)	Minimum 1 per SDG/per parameter/per matrix/per concentration level
Reagent Blank	Accuracy/Bias (Contamination)	As per method and based on DQOs
Storage Blank	Accuracy/Bias (Contamination)	Minimum 1 per aqueous VOA SDG
Instrument (System) Blank	Accuracy/Bias (Contamination)	As per method and based on DQOs
Laboratory Duplicates	Precision	Minimum 1 per inorganic SDG/per parameter/per matrix/per concentration level
Internal Standards	Precision and Accuracy/Bias	As per method and based on DQOs
Analytical Replicates	Precision	As per method and based on DQOs
Matrix Spike Duplicates	Precision and Bias	Minimum 1 set per organic SDG/per parameter/per matrix/per concentration level
Matrix Spike	Bias	Minimum 1 per inorganic SDG/per parameter/per matrix/per concentration level
PES –Single Blind and Double Blind	Bias	Minimum 1 per SDG/per parameter/per matrix/per concentration level
Surrogate Spikes	Bias	As per method and based on DQOs
Laboratory Control Sample (LCS) – Zero Blind PES	Bias	As per method and based on DQOs
Laboratory Fortified Blank (LFB)[3] – Zero Blind PES	Bias and Sensitivity	Minimum 1 per aqueous low-concentration Organic SDG/analytical parameter As per method and based on DQOs for other parameters, matrices, and concentration levels
Method Detection Limit Studies (MDL)	Sensitivity	Annually per laboratory/per parameter/per matrix/per concentration level
Instrument Performance Check Samples	Sensitivity	As per method and based on DQOs
Initial Calibration	Accuracy	After initial instrument setup, as per method and when calibration verification fails

Table 4. Types of Field Analytical and Fixed Laboratory QC Checks/Samples and Recommended Frequency (Continued)

Analytical QC	Data Quality Indicators[1]	Recommended Frequency[2]
Continuing Calibration and/or Calibration Verification Checks	Accuracy	Minimum 1 per analytical shift and more frequently as per method and based on DQOs
Biological		
Biological QC Checks (Biological Specimen Samples)	Reproducibility, etc.	As per method and based on DQOs

[1]See Table 5 for additional DQI information.
[2]The QAPP should indicate any deviations from recommended frequencies and provide justification.
[3]A laboratory fortified blank (LFB) is defined as an aliquot of reagent matrix spiked with several or all of the target compounds/analytes at or below their quantitation limits.

Table 5. Information Derived from Quality Control Checks and Samples

Data Quality Indicator (Type of Information Provided)	QC Checks and Samples	Sources of Measurement Error										
		Sample Collection				Sample Transport	Laboratory					
		Sampling Equipment	Sample Container	Preservation Technique	Sample Matrix	Shipment Process	Sample Storage @ Laboratory	Sample Preparation Reagents	Sample Preparation Equipment	Analytical Method Reagents	Analytical Equipment	Purpose
Accuracy/Bias (contamination)	**Equipment Blank (Rinsate blank)**	X	X	X		X	X	X	X	X	X	To evaluate carryover contamination resulting from successive use of sampling equipment.
	Bottle Blank per Lot #		X					X	X	X	X	To evaluate contamination introduced from the sample container.
	VOA Trip Blank		X	X		X	X	X	X	X	X	To evaluate contamination introduced during shipment.
	Storage Blank						X	X	X	X	X	To evaluate cross-contamination introduced during sample storage.
	Method Blank							X	X	X	X	To evaluate contamination introduced during sample preparation and/or analysis by laboratory, including reagents, equipment, sample handling, and ambient laboratory conditions.
	Reagent Blank per Lot #							X	X	X	X	To evaluate contamination introduced by specific method reagents.
	Instrument (system) Blank									X	X	To evaluate contamination originating from the analytical reagents instrumentation.
Accuracy/Bias (preservation)	**Cooler Temp. Blank – VOA only**			X								To evaluate whether or not samples were adequately cooled during shipment.

Table 5. Information Derived from Quality Control Checks and Samples (continued)

Data Quality Indicator (Type of Information Provided)	QC Checks and Samples	Sources of Measurement Error										
		Sample Collection				Sample Transport	Laboratory					
		Sampling Equipment	Sample Container	Preservation Technique	Sample Matrix	Shipment Process	Sample Storage @ Laboratory	Sample Preparation Reagents	Sample Preparation Equipment	Analytical Method Reagents	Analytical Equipment	Purpose
Accuracy/Bias	Matrix Spike				X			X	X	X	X	To determine laboratory preparatory and analytical bias for specific compounds in specific sample matrices.
	Surrogate Spike				X			X	X	X	X	To evaluate laboratory preparatory and analytical bias for specific sample matrices.
	Laboratory Control Sample (LCS) -- Zero Blind							X	X	X	X	To evaluate the laboratory's ability to accurately identify and quantitate target compounds in a reference matrix at a known concentration, usually midrange of the calibration curve.
	Performance Evaluation Sample – Ampulated Single Blind							X	X	X	X	To evaluate sample handling procedures from field to laboratory. To evaluate the laboratory's ability to accurately identify and quantitate target compounds in a reference matrix. Frequently used for data quality assessments and for laboratory self-assessments and external assessments, i.e., preawards and laboratory TSAs.
	Performance Evaluation Sample – Full Volume Single Blind		X	X		X	X	X	X	X	X	

Table 5 Information Derived from Quality Control Checks and Samples (continued)

Data Quality Indicator (Type of Information Provided)	QC Checks and Samples	Sources of Measurement Error											
		Sample Collection				Sample Transport	Laboratory						
		Sampling Equipment	Sample Container	Preservation Technique	Sample Matrix	Shipment Process	Sample Storage @ Laboratory	Sample Preparation Reagents	Sample Preparation Equipment	Analytical Method Reagents	Analytical Equipment	Purpose
Accuracy/Bias (continued)	Performance Evaluation Sample – Double Blind		X	X		X	X	X	X	X	X	To evaluate sample handling procedures from field to laboratory. To evaluate the laboratory's ability to accurately identify and quantitate target compounds in a reference matrix.
	Laboratory Fortified Blank (LFB)							X	X	X	X	A type of LCS used to evaluate laboratory (preparatory and analytical) sensitivity and bias for specific compounds in a reference matrix at the quantitation limit concentrations.
	Initial Calibration									X	X	To ensure that the instrument is capable of producing acceptable qualitative and quantitative data.
	Continuing Calibration/ Continuing Calibration Verification									X	X	To ensure the accuracy and stability of the instrument response.
	Instrument Performance Check Sample									X	X	To verify that an instrument can accurately identify and quantitate target analytes at specific concentration levels.

Table 5 Information Derived from Quality Control Checks and Samples (continued)

Data Quality Indicator (Type of Information Provided)	QC Checks and Samples	Sources of Measurement Error										
		Sample Collection				Sample Transport	Laboratory					
		Sampling Equipment	Sample Container	Preservation Technique	Sample Matrix	Shipment Process	Sample Storage @ Laboratory	Sample Preparation Reagents	Sample Preparation Equipment	Analytical Method Reagents	Analytical Equipment	Purpose
Sensitivity	**LFB**							X	X	X	X	A type of LCS used to evaluate laboratory (preparatory and analytical) sensitivity and bias for specific compounds in a reference matrix at the quantitation limit concentrations.
	MDL Studies				X (if performed using same reference matrix)			X	X	X	X	A statistical determination that defines the minimum concentration of a substance that can be measured and reported with 99% confidence that the analyte concentration is greater than zero. Quantitation limits (QLs)/practical QLs (PQLs) are generally 3-10 times the MDL.
	Low Point of Initial Calibration Curve									X	X	To ensure that the instrument is capable of producing acceptable qualitative and quantitative data at the lowest concentration that sample results will be reported; the quantitation limit.

Table 5 Information Derived from Quality Control Checks and Samples (continued)

Data Quality Indicator (Type of Information Provided)	QC Checks and QC Samples	Sources of Measurement Error										
		Sample Collection				Sample Transport	Laboratory					
		Sampling Equipment	Sample Container	Preservation Technique	Sample Matrix	Shipment Process	Sample Storage @ Laboratory	Sample Preparation Reagents	Sample Preparation Equipment	Analytical Method Reagents	Analytical Equipment	Purpose
Precision	**Field Duplicates**	X	X	X	X	X	X	X	X	X	X	To measure overall precision by evaluating cumulative effects of both field and laboratory precision.
	Laboratory Duplicates				X			X	X	X	X	To evaluate laboratory preparatory and analytical precision.
	Matrix Spike Duplicates				X			X	X	X	X	To determine laboratory preparatory and analytical bias and precision for specific compounds in specific sample matrices.
	Analytical Replicates (e.g., duplicate injections)										X	To evaluate analytical precision for determinative instrumentation.
	Internal Standards										X	To evaluate biological instrument precision and stability.
Interlaboratory Comparability	**Field Splits**					X	X	X	X	X	X	To evaluate sample handling procedures from field to laboratory and to evaluate interlaboratory comparability and precision.
Reproducibility	**Biological QC Check**	X	X	X		X	X	X	X	X	X	To evaluate biological sorting reproducibility between laboratories and/or analysts.

3.3.1.2.1 *Field Analytical QC*

Provide tables showing field analytical QC that contain the information shown in the headings in Figure 27. Figure 27 corresponds to Optional Worksheet #23a in the QAPP workbook.

If method/SOP QC acceptance limits exceed the project-specific measurement performance criteria, then the data obtained may be unusable in making project decisions.

Figure 27. Field Analytical QC Sample Table

Medium/Matrix	
Sampling SOP	
Analytical Parameter	
Concentration Level	
Analytical Method/ SOP Reference	
Field Analytical Organization	
No. of Sample Locations	

Laboratory QC:	**Frequency/Number**	**Method/SOP QC Acceptance Limits**	**Corrective Action (CA)**	**Person(s) Responsible for CA**	**Data Quality Indicator (DQI)**	**Measurement Performance Criteria**

If analytical parameters have multiple analytes, provide a table that shows the field analytical method and indicates SOP precision and accuracy as shown in Figure 28. Figure 28 corresponds to Optional Worksheet #23b in the QAPP workbook.

Figure 28. Field Analytical Method/SOP Precision and Accuracy Table

Sampling SOP:
Analytical Method/SOP:

Analyte	**Achievable Sensitivity/Quantitation Limits**	**Field Analytical Precision**	**Field Analytical Accuracy/Bias**

If field screening techniques are used, provide a decision tree or logic diagram to describe how samples will be selected for subsequent confirmatory analysis.

3.3.1.2.2 *Fixed Laboratory QC*

Provide information on analytical QC sample for fixed laboratories as shown in Figure 29. Figure 29 corresponds to Optional Worksheet #24a in the QAPP workbook.

If method/SOP QC acceptance limits exceed the project-specific measurement performance criteria, then the data obtained may be unusable in making project decisions.

Figure 29. Fixed Laboratory Analytical QC Sample Table

Medium/Matrix	
Sampling SOP	
Analytical Parameter	
Concentration Level	
Analytical Method/ SOP Reference	
Laboratory Name	
No. of Sample Locations	

Laboratory QC:	Frequency/Number	Method/SOP QC Acceptance Limits	Corrective Action (CA)	Person(s) Responsible for CA	Data Quality Indicator (DQI)	Measurement Performance Criteria

If analytical parameters have multiple analytes, provide a Fixed Laboratory Method/SOP Precision and Accuracy Table that contains the information shown in Figure 30. Figure 30 corresponds to Optional Worksheet #24b in the QAPP workbook.

Figure 30. Laboratory Method/SOP Precision and Accuracy Table

Sampling SOP:
Analytical Method/SOP:

Analyte	Achievable Laboratory Sensitivity/Quantitation Limits	Analytical Precision	Analytical Accuracy/Bias

3.4 Data Acquisition Tasks

3.4.1 Data Acquisition Requirements (Non-Direct Measurements)

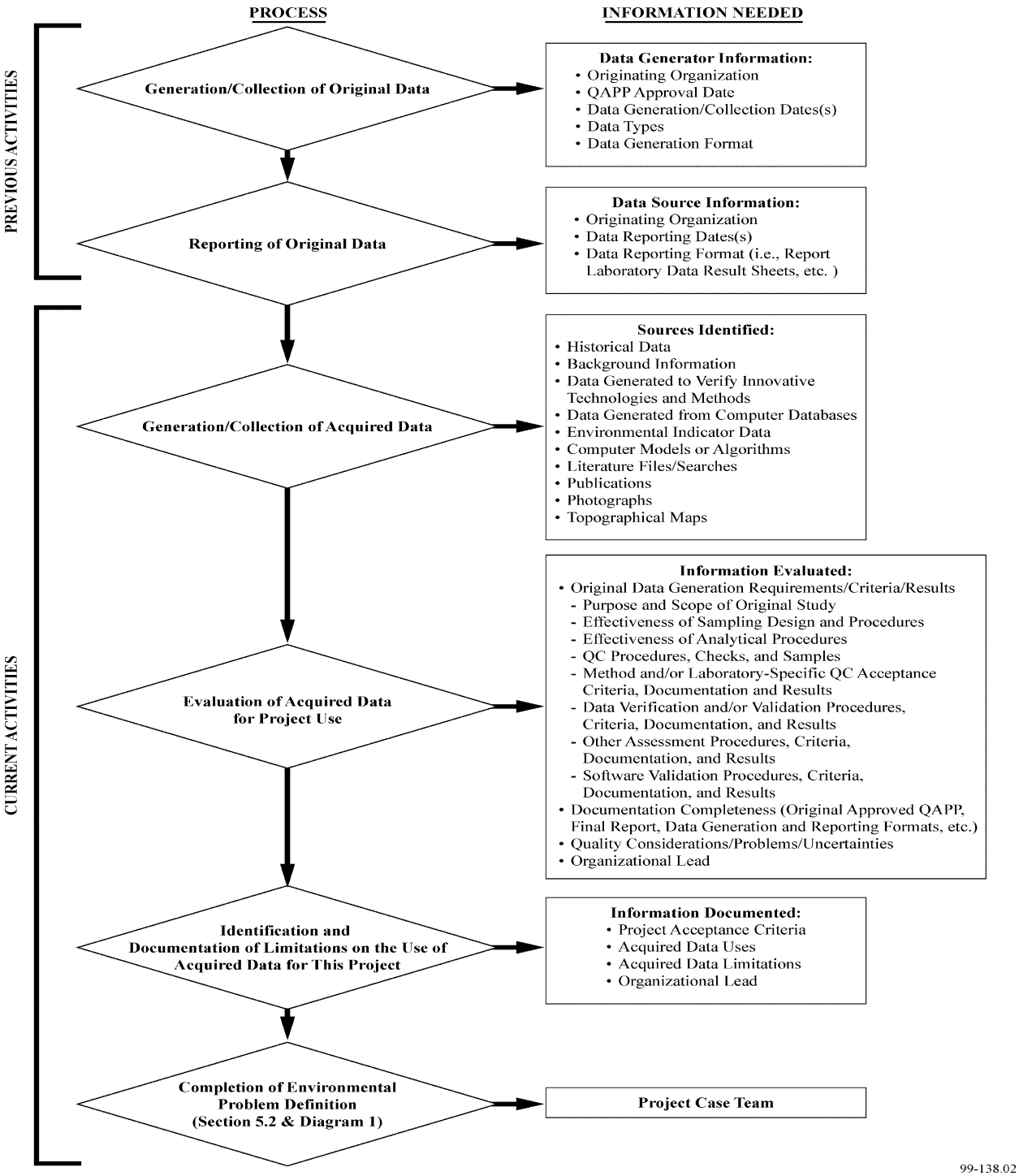
This section of the QAPP identifies the sources of previously collected data and other information that will be used to make project decisions. It is essential to identify the limitations on the use of acquired data, since using data and information that are not generated under the same quality objectives as the current investigation may result in erroneous decisions. Figure 31 outlines the process used to evaluate acquired data.

The term "acquired data" is defined as information from any source outside of the current activity that may affect the environmental decision-making process. Secondary sources of acquired data and information include, but are not limited to:

- Historical data (e.g., from an organization's or facility's corporate records and/or Federal, State, or local records pertaining to previous monitoring events, site assessments, investigations, etc.). Historical data may be used in QAPP Section 2.5.2 to describe the site history and define the environmental problem.
- Background information/data from an organization's/facility's corporate records and/or Federal, State, or local records pertaining to site-specific industrial processes, process by-products, past and current chemical uses, raw material and finished product testing, waste testing and disposal practices, and potential chemical breakdown products.
- Data generated to verify innovative technologies and methods.
- Data generated from computer databases (such as manufacturers' process/product information or waste management or effluent information).
- Environmental indicator data obtained from Federal, State, or local records.
- Computer models or algorithms.
- Literature files/searches.
- Publications.
- Photographs.
- Topographical maps.

Note that the quality of acquired data will become an increasingly important issue for many EPA programs. To ensure that correct environmental decisions are made, the same care should be taken using secondary data as is taken in generating new data.

Figure 31. Acquired Data Evaluation Process



All non-direct measurement data and information that will be used for this project, and their originating sources, should be provided in tabular format. Specify how the acquired data and information will be used and the limitations on their use. (Note: Since this table cannot capture all required information regarding acquired data, it will be necessary to provide additional information in the text.) Figure 32 shows headings for a table that provides non-direct measurements criteria and limitations. Figure 32 corresponds to Optional Worksheet #25 in the QAPP workbook.

Figure 32. Non-Direct Measurements Criteria and Limitations Table

Non-Direct Measurement (Secondary Data)	Data Source (Originating Organization, Report Title, and Date)	Data Generator(s) (Originating Org., Data Types, Data Generation/Collection Dates)	How Data Will Be Used	Limitations on Data Use

Evaluate and discuss the quality of all non-direct measurement data as well as the completeness of the data documentation. Identify the generator(s) of the data, dates the data were generated/collected and reported, source(s) from which the data were obtained, and procedures originally used to generate and collect the data (including sampling, analytical, and assessment procedures). If known, describe all QC procedures, checks, and samples that were analyzed with the data set. Describe the method and/or laboratory-specific QC acceptance criteria used for data generation and ascertain whether or not data were verified and/or validated. If data were verified/validated, describe the criteria and procedures used, the documentation provided, as well as the results obtained from previous verification/validation activities. Refer to Section 5.1 for a complete discussion of data verification and validation.

In the text, discuss the quality of the previously generated data, addressing the following issues:

- If the data were generated under an approved QAPP or other sampling document, reference the document by title, date, originating organization, and approving organization.
- Evaluate the purpose and scope of previous studies and compare with current study objectives. Evaluate similarities and differences of the measurement performance criteria and data quality indicators.
- Evaluate the design and implementation of previous studies by examining the following issues:
  - Whether the study was conducted properly
  - Whether control responses were within acceptable limits
  - Whether standard sampling and analytical methods and/or standard QA/QC protocols were available and followed by the study.

- Include a brief description of the sampling procedures per matrix type (e.g., grab/grid for surficial soils, etc.) and analytical procedures per matrix type (e.g., SW-846 Method 3550/8270 for surficial soils, etc.).
- If performance and/or system audits and/or split sampling activities were performed, synopsize the results of those audits/activities.
- If data were verified and/or validated, reference the verification and/or validation procedure by title, date, and originating organization.
- If data were obtained from a computer model/algorithm, provide a brief description of the validation of that computer software.
- If data were obtained from a database, provide a brief discussion on the integrity/accuracy of the database information.
- Discuss the adequacy of the original QA documentation under which secondary data were generated. For example, if insufficient raw analytical data are available to verify that an instrument was calibrated accurately, then the secondary data may not be usable for their intended purpose.

Discuss all possible limitations on the use of previously generated/collected non-direct measurement data for this project based on the uncertainty surrounding their quality. Discuss the nature and magnitude of that uncertainty. For example, discuss the impact of using unvalidated historical monitoring data to answer project questions and support project decisions. Unvalidated data may be scientifically inaccurate or may not meet the objectives of the user. Also, discuss the impact of using acquired data with known analytical or sampling inaccuracy or bias and/or imprecision. For example, document the sampling and analytical methods used to collect and analyze soil VOA samples and discuss possible low bias in sample results.

Document the acceptance criteria used to determine whether those previously generated/collected non-direct measurement data/information are usable for this project. For example, if acquired drinking water data will be used to answer project questions, then the QAPP should state that only data generated by EPA/State-certified or NELAP-accredited Safe Drinking Water Act (SDWA) laboratories will be used for this project. Provide comparability criteria for previously generated/collected non-direct measurement data (e.g., historical routine monitoring data) and the data generated for this project.

3.5 Data Management Tasks

3.5.1 Documentation, Records, and Data Management

All project data and information must be documented in a format that is usable by project personnel. This section of the QAPP describes how project data and information will be documented, tracked,

and managed from their generation in the field to final use and storage in a manner that ensures data integrity and defensibility.

3.5.1.1 Project Documentation and Records

Provide a table that lists the project documents and records that will be generated for every aspect of the project, including but not limited to the following:

1. Sample Collection Records
   - Field logbooks/notes
   - Field data collection sheets
   - Chain-of-custody records
   - Custody seals
   - Sample tags
   - Telephone logs
   - Airbills
   - Corrective action reports

2. Field Analysis Records
   - Chain-of-custody records
   - Sample receipt forms/sample tracking forms
   - Preparation and analysis forms and/or logbooks
   - Tabulated data summary forms and raw data for field samples, standards, QC checks, and QC samples
   - Other project-specific documents, such as telephone logs, MDL studies, Initial Precision and Accuracy (IPA) Tests, and corrective action reports

3. Fixed Laboratory Records
   - Chain-of-custody records
   - Sample receipt forms/sample tracking forms
   - Preparation and analysis forms and/or logbooks
   - Tabulated data summary forms and raw data for field samples, standards, QC checks, and QC samples
   - Other project-specific documents in the laboratory's possession, such as telephone logs, MDL studies, IPA Tests, Laboratory Pre-award Documentation (including pre-award PE sample data and relevant copies of proposal package), and corrective action reports

4. Project Data Assessment Records
   - Field sampling audit checklists
   - Field analytical audit checklists
   - Fixed laboratory audit checklists
   - PE sample results
   - Data validation reports
   - Telephone logs
   - Corrective action reports

Figure 33 shows examples of headings for a table listing project documents and records. Figure 33 corresponds with Optional Worksheet #26 in the QAPP workbook.

Figure 33. Project Documents and Records Table

Sample Collection Records	Field Analysis Records	Fixed Laboratory Records	Data Assessment Records	Other

3.5.1.2 Field Analysis Data Package Deliverables

In this section of the QAPP, specify required data package turnaround times for each field analytical parameter. Itemize the required data package deliverables for all field analytical data generated in the field.

- ***Field Analytical-Screening Data.*** The requirements for field analysis (screening) data packages are project-specific. In addition, the usability of field screening data depends on the project quality objectives and the comparability of those data to the full protocol (on-site mobile laboratory and/or fixed laboratory) confirmatory data. If comparability issues arise during the comparison of field screening and full-protocol data and they cannot be resolved due to the nonexistence and/or unavailability of sufficient documentation for the field screening data, then the achievement of the project objectives may be jeopardized since those field screening data cannot be used to make the planned project decisions.

- ***Field Analytical Data, Definitive Data, and Field Measurement.*** If field measurements (for example, specific conductance, temperature, DO, pH, turbidity, ORP/Eh, and residual chlorine) are taken, then all field and QC sample results, calibrations, and calibration verifications should be recorded in a field log notebook to ensure proper verification of sample results. If field analytical data are generated for definitive purposes, that is, by full-protocol methods, then a complete data package should be generated to ensure that data can be properly validated (see Tables 6 and 7).

If complete field analysis data packages (i.e., original raw data) are not required deliverables, then the QAPP must justify this decision and specify which project data will be kept by the field analytical unit, where the data will be stored (provide the organization's name and address and identify exact location in building), and how long it will be stored (the length of required record storage is program-dependent).

Even if complete data packages are not required deliverables in the QAPP, all hard-copy and electronic data/information relevant to the project must be archived by the field analytical unit in one location to ensure their availability for potential future retrieval/use.

For all data collection events, in order to facilitate possible future review, it is strongly recommended that raw data, such as magnetic tapes of all field samples, QC checks, and samples, standards, and blanks be archived, if applicable, to the analytical technique, and be available on request for a minimum of 5 years from the date of generation.

3.5.1.3 Fixed Laboratory Data Package Deliverables

Specify required data package turnaround times for each analytical parameter for each fixed laboratory retained to provide analytical services. Itemize the required data package deliverables for all data generated in a fixed laboratory.

For all data collection events, a complete laboratory data package (as itemized in Tables 5 and 6) should be provided for each set of samples designated as a group (sample delivery group, or SDG). A good example of the requirements for a data package for 18 different analytical methods is found in the EPA Region 9 draft report, *Laboratory Documentation Requirements for Data Validation*, July 1997 (9QA-07-97) (available at http://www.epa.gov/region09/qa/r9_qadocs.html).

It is recommended that magnetic tapes of all field samples, QC checks and samples, standards, and blanks be archived, if applicable, to the analytical technique, and be available upon request for 1 year from date of generation.

Complete laboratory data package deliverables often include the following documents, as shown on Tables 6 and 7.

Table 6. Recommended Complete Laboratory Data Package Documentation

COMPLETE LABORATORY DATA PACKAGE DOCUMENTATION

1. Original *sample data package*, including tabulated summary forms and raw data for field samples, standards, QC samples, and blanks (see below, Sample Data Package Documentation)
2. A completed and signed Document Inventory Sheet used to record the inventory of the complete laboratory data package
3. All original shipping documents including, but not limited to, the following documents:
    a. Client chain-of-custody records/traffic reports
    b. Airbills
    c. Custody seals
    d. Sample tags (if present)
4. All original receiving documents including, but not limited to, the following documents:
    a. Sample log-in sheet, used to document the receipt and inspection of samples and containers
    b. Other receiving forms or copies of receiving logbooks
    c. Sample Delivery Group cover sheet identifying the samples received for the group of samples in the data package
5. All original laboratory records of sample transfer, preparation, and analysis, including, but not limited to, the following documents:
    a. Original preparation and analysis forms and/or copies of preparation and analysis logbook pages
    b. Internal sample and sample extract (organics) or sample digestate/distillate (inorganics) transfer chain-of-custody records
6. All other original project-specific documents in the possession of the laboratory including, but not limited to, the following documents:
    a. Telephone contact logs
    b. Copies of personal logbook pages
    c. All handwritten project-specific notes
    d. All other project-specific documents not covered by the above

SAMPLE DATA PACKAGE DOCUMENTATION

1. Narrative
2. Tabulated summary forms for
    - Field sample data (listed by increasing client sample identification number)
    - Laboratory standards (in chronological order by instrument)
    - QC samples (in chronological order by type of QC sample)
    - Blanks (in chronological order by instrument)
3. Raw data for field samples, laboratory standards, QC samples, and blanks (in chronological order by instrument)
4. Laboratory logbook pages for preparation and analysis of field samples, standards, QC samples, and blanks
5. Chain-of-custody records
6. Other project-specific documents in the laboratory's possession

For organic data, each type of tabulated summary form must be grouped by fraction (volatile, semivolatile, pesticide/PCB). Depending on whether the data package contains organic or inorganic analytical data, the required tabulated forms and format for field samples, standards, QC samples, and blanks will vary.

Table 7. Recommended Laboratory Data Package Elements

DATA PACKAGE ELEMENTS	VOA	SVOA	PEST/PCB	METALS	CN	OTHER
● INVENTORY SHEET (Org. and Inorg. DC-2 Form)	X	X	X	X	X	X
● NARRATIVE (Org. Narrative, Inorg. Cover Page)	X	X	X	X	X	X
● EPA SHIPPING/RECEIVING DOCUMENTS AND INTERNAL LABORATORY CHAIN-OF-CUSTODY RECORDS:						
- Airbills	X	X	X	X	X	X
- Chain-of-Custody Records/Forms (Traffic Report)	X	X	X	X	X	X
- Sample Tags	X	X	X	X	X	X
- Sample Log-In Sheet (Org. and Inorg. DC-1 Form)	X	X	X	X	X	X
- Miscellaneous Shipping/Receiving Records	X	X	X	X	X	X
- Internal Lab. Sample Transfer Records and Tracking Sheets	X	X	X	X	X	X
● SAMPLE DATA:						
- Tabulated Summary Form for Field Sample and PE Sample Results (Org. and Inorg. Form I)	X	X	X	X	X	X
- Tentatively Identified Compounds Tabulated Summary Form (Org. Form I TIC)	X	X				
- Reconstructed total ion chromatogram (RIC) for each sample	X	X				
- Raw spectra of target compound and background-subtracted spectrum of target compound for each sample	X	X				
- Mass spectra of all reported TICs/three best library matches for each sample	X	X				
- Chromatograms from both columns for each sample			X			
- GC integration report or data system printouts and calibration plots for each sample			X			
- PEST/PCB Identification Tabulated Summary Form (Org. Form X)			X			
- For PEST/PCBs confirmed by GC/MS, copies of raw spectra and background-subtracted spectrum of target compounds			X			
- GPC sample chromatograms		X	X			
- UFP-QAPP Manual worksheets	X	X	X	X	X	X
- Sample preparation/extraction/digestion log (Inorg. Form XIII) and logbook pages	X	X	X	X	X	X

VOA = volatile organic compounds
SVOA = semivolatile organic compounds
PEST = pesticide organic compounds
PCB = polychlorinated biphenyls
CN = cyanide
Other = other parameters
( ) = Form Number, refer to CLP SOW forms if CLP is used

Table 7. Recommended Laboratory Data Package Elements (continued)

DATA PACKAGE ELEMENTS	VOA	SVOA	PEST/PCB	METALS	CN	OTHER
● SAMPLE DATA (continued):						
- Sample analysis run log (Inorg. Form XIV) and logbook pages	X	X	X	X	X	X
- ICP raw data				X		
- Furnace AA raw data				X		
- Mercury raw data				X		
- Cyanide raw data					X	
- Other analytical raw data						X
● STANDARDS DATA:						
- Method Detection Limit Study Tabulated Summary Form	X	X	X	X	X	X
- Initial Calibration Tabulated Summary Form (Org. Form VI, Inorg. Form IIA)	X	X	X	X	X	X
- Continuing Calibration Tabulated Summary Form (Org. Form VII, Inorg. Form IIA)	X	X	X	X	X	X
- RICs and quantitation reports for all GC/MS standards	X	X				
- Pesticide Analyte Resolution Tabulated Summary Form (Org. Form VI, Pest-4)			X			
- Pesticides Calibration Verification Tabulated Summary Form (Org. Form VII, Pest-1 and Pest-2)			X			
- Pesticide Analytical Sequence Tabulated Summary Form (Org. Form VIII-Pest)			X			
- GC chromatograms and data system printouts for all GC standards			X			X
- For pesticides/aroclors confirmed by GC/MS, copies of spectra for standards used			X			
- GPC Calibration Tabulated Summary Form (Org. Form IX, Pest-2)			X			
- Florisil Cartridge Check Tabulated Summary Form (Org. Form IX, Pest-1)			X			
- Instrument Detection Limits Tabulated Summary Form (Inorg. Form X)				X	X	
- ICP Interelement Correction Factors Tabulated Summary Form (Inorg. Form XIA and XIB)				X		
- ICP Linear Ranges Tabulated Summary Form (Inorg. Form XII)				X		
- CRDL Standards for AA and ICP Tabulated Summary Form (Inorg. Form IIB)				X		
- Standards preparation logbook pages	X	X	X	X	X	X

VOA = volatile organic compounds
SVOA = semivolatile organic compounds
PEST = pesticide organic compounds
PCB = polychlorinated biphenyls
CN = cyanide
Other = other parameters
( ) = Form Number, refer to CLP SOW forms if CLP is used

Table 7. Recommended Laboratory Data Package Elements (continued)

DATA PACKAGE ELEMENTS	VOA	SVOA	PEST/PCB	METALS	CN	OTHER
● QC DATA:						
- Tuning and Mass Calibration Tabulated Summary Form (Org. Form V)	X	X				
- Surrogate Percent Recovery Tabulated Summary Form (Org. Form II)	X	X	X			
- MS/MSD Recovery Tabulated Summary Form (Org. Form III)	X	X	X			
- Method Blank Tabulated Summary Form (Org. Form IV and Inorg. Form III)	X	X	X	X	X	
- Internal Standard Area and RT Tabulated Summary Form (Org. Form VIII)	X	X				
- QC Raw Data - RICs, chromatograms, quantitation reports, integration reports, mass spectra, etc.	X	X	X			X
- ICP Interference Check Sample Tabulated Summary Form (Inorg. Form IV)				X		
- Spike Sample Recovery Tabulated Summary Form (Inorg. Form VA)				X	X	
- Post Digest Spike Sample Recovery Tabulated Summary Form (Inorg. Form VB)				X	X	
- Duplicates Tabulated Summary Form (Inorg. Form VI)				X	X	
- Internal Laboratory Control Sample Tabulated Summary Form (Inorg. Form VII)				X	X	
- Standard Addition Results Tabulated Summary Form (Inorg. Form VIII)				X		
- ICP Serial Dilutions Tabulated Summary Form (Inorg. Form IX)				X		
- QC raw data – ICP, furnace, mercury, computer printouts, etc.				X	X	X
- QC sample preparation logbook pages	X	X	X	X	X	X
● MISCELLANEOUS DATA:						
- Original preparation and analysis forms or copies of preparation and analysis logbook pages	X	X	X	X	X	X
- Screening records	X	X	X			X
- All instrument output, including strip charts, from screening activities	X	X	X			X
- Preparation logs raw data	X	X	X	X	X	X
- Percent solids determination log	X	X	X	X	X	X
- Other records (e.g., telephone communication log)	X	X	X	X	X	X

VOA = volatile organic compounds
SVOA = semivolatile organic compounds
PEST = pesticide organic compounds
PCB = polychlorinated biphenyls
CN = cyanide
Other = other parameters
( ) = Form Number, refer to CLP SOW forms if CLP is used

3.5.1.4 Data Reporting Formats

Discuss procedures and/or SOPs for recording data, including guidelines for recording (manually, legibly in ink, and initialed and dated by the responsible person) and correcting data (e.g., single line drawn through errors, initialed and dated by the responsible person).

Include, as an attachment to the QAPP or within the LQAP or Laboratory QA Manual, examples of hard-copy data reporting forms and all verification checklists/forms. If applicable, discuss specifications for electronic data deliverables' format and content and computer configuration requirements. Include, as an attachment to the QAPP or within the LQAP or Laboratory QA Manual, examples of all electronic data deliverable forms.

3.5.1.5 Data Handling and Management

Describe all computerized and manual procedures that trace the path of all data from generation to final use and storage. Alternatively, include applicable SOPs as attachments to the QAPP. Also describe the associated quality checks for error detection that are performed to ensure data integrity. The following data management steps should be addressed:

Request to Reviewers

The IDQTF Workgroup would like to incorporate references to policies for data handling and management into this section. EPA Directive 2185, Good Automatic Laboratory Practices (GALP), provides electronic data handling and management guidance and could be referenced. However, because this section deals with data handling and management in general and not specifically electronic data, the workgroup is seeking references to policies that address general data management. In addition, because this UFP-QAPP Manual applies to agencies other than EPA, the workgroup is seeking references to policies from other Federal agencies as well. Do Federal agencies other than EPA adhere to GALP? What other data management and handling policies exist?

- Data Recording
  - Provide examples of data entry forms.
  - Describe internal checks to detect errors such as transcription and calculation errors, the resultant documentation generated, and responsible personnel. Provide examples of all verification checklists/forms.

- Data Transformations/Data Reduction
  - Provide formulas used in data conversions, e.g., calculation of dry weight field sample concentrations.
  - Describe when and how data conversion procedures are performed, how they are checked, the resultant documentation generated, and responsible personnel.
  - Describe all data manipulations involved in reducing raw data to reportable data, as well as responsible personnel.

- Provide an example of how raw data are reduced for all manual and automated calculations, e.g., calculation of sample concentrations from peak areas.
- Provide references to specific software documentation for automated data processing.
- Describe internal checks to detect errors, the resultant documentation generated, and responsible personnel. Provide examples of all verification checklists/forms.
- Indicate the number of significant figures.

- Data Transfer/Transmittal
  - Identify electronic data transfer software.
  - Provide examples of electronic data transfer forms.
  - Describe manual data transcription and electronic transmittal procedures, the resultant documentation generated, and responsible personnel.
  - Describe internal checks to detect errors, the resultant documentation generated, and responsible personnel. Provide examples of all verification checklists/forms.

- Data Analysis
  - Identify and describe the data equipment and computer hardware and software that will be used to process, compile, and analyze project data (e.g., the Laboratory Information Management Systems, or LIMS), and acquired/secondary data (as discussed in Section 3.4.1).
  - Describe in detail, and/or include as attachments to the QAPP, the computer models and/or algorithms that will be used for data analysis and justify their use for this project.
  - Identify hardware requirements (specifically computer disk space, memory, and speed) that will be required to run and compile modeling data.
  - Describe any specific performance requirements for the hardware/software configuration, model, or algorithm.
  - Describe computer test procedures and manual verification check procedures used to demonstrate acceptability of hardware/software configurations and computer programs and models, the resultant documentation generated, and personnel responsible. Provide examples of check data and examples of all verification checklists/forms.

- Data Assessment
  - Describe in detail, and/or include as attachments to the QAPP, the computer validation programs that will be used to validate data.
  - Describe in detail, and/or include as attachments to the QAPP, statistical computer programs that will be used to assess data.
  - Identify hardware requirements (specifically computer disk space, memory, and speed) that will be required to run validation and/or assessment software.
  - Describe computer test procedures and manual verification check procedures used to demonstrate acceptability of hardware/software configurations and computer programs,

the resultant documentation generated, and personnel responsible. Provide examples of all verification checklists/forms.
- Indicate the anticipated organization for data assessment/validation.

3.5.1.6 Data Tracking and Control

- Data Tracking
  - Describe, and/or include as attachments to the QAPP, procedures for tracking data as they are collected, transformed/reduced, transmitted, and analyzed; the resultant documentation generated; and the responsible personnel.

- Data Storage, Archival, and Retrieval
  - Describe, and/or include as attachments to the QAPP, data storage, archival, and retrieval procedures for all project data, documents, records, and reports. Differentiate between hard-copy and electronic data and information.
  - Identify specific project data, documents, records, reports, etc. that will be stored and/or archived. Differentiate between hard-copy and electronic data and information. Differentiate between documentation stored at a subcontracted laboratory and documentation archived by the Lead Organization. If data package deliverables do not include all data documentation, describe what data (for field screening, field analysis, and fixed laboratory) will be kept by which laboratory or other organization, and provide the exact physical locations (i.e., complete laboratory/organization name, address, and specific location in the building).
  - Identify the organizations and personnel that are responsible for storing/archiving/ retrieving specific project documents. Identify the responsible document control personnel, including organizational affiliation, telephone, and fax number.
  - Describe where the documents will be stored during the project and where the documents will be archived. Provide exact locations (organization name, complete address, and specific location in building) and timeframes in which documents will be moved from one location to another.
  - Indicate when documents will be archived to a final location.

- Data Security
  - Describe, and/or include as attachments to the QAPP, procedures for data security.
  - Describe, and/or include as attachments to the QAPP, procedures for computer security.

4.0 ASSESSMENT AND OVERSIGHT ELEMENTS

This QAPP element group ensures that planned project activities are implemented as described in the QAPP and that reports are provided to apprise management of the project status and any quality issues that arise during implementation. Assessment activities ensure that the resultant data quality is adequate for its intended use and that appropriate responses are in place to address nonconformances and deviations from the QAPP.

Frequently, deviations from the QAPP are identified by project personnel without the benefit of formal, scheduled assessments. This section also addresses those situations and describes the process by which the need for corrective action is documented, reported, and implemented and its effectiveness assessed.

4.1 Assessments and Response Actions

This section of the QAPP identifies the number, frequency, and types of planned assessment activities that will be performed for the project. Assessments should be conducted periodically throughout the project by entities internal and/or external to the project to ensure that usable data are generated. In addition, oversight assessments should be performed by the approval authority to identify and correct nonconformances so that project quality objectives can be achieved.

Appropriately scheduled assessments allow management to implement corrective action measures in a timely manner, thereby minimizing the impact of nonconformance on achieving project quality objectives. The project quality objectives dictate the type, frequency, and extent of the assessments that should be performed.

Choose assessments that identify activities with the most influence on data quality and that provide information about potential problems and mistakes. Sampling error is generally thought to contribute the majority of the measurement error associated with project data, where:

Measurement Error = Sampling Error + Analytical Error

Therefore, it is recommended that all data generation/collection operations include at least one field sampling technical systems audit (TSA) at the start of field sampling activities so that effective corrective action measures can be implemented to mitigate the extent and impact of identified nonconformances. Investigative projects and routine monitoring projects should also include field analytical, field laboratory, and/or fixed laboratory TSAs as appropriate. A remedial investigation/ feasibility study with known human health and/or ecological risks should include comprehensive assessments of field sampling and field analytical/field laboratory/fixed laboratory measurement

procedures and proposed remediation technologies, and an evaluation of the risk assessment procedures that will be employed.

Describe activities for identifying and correcting any problems encountered during the project. Optional Worksheet #27a in the QAPP workbook can be used for this purpose.

4.1.1 Planned Assessments

If no assessments (audits) are planned, document that fact and provide a justification in this section of the QAPP.

If assessments are planned, provide a table that includes the information shown in Figure 34. Figure 34 corresponds to Optional Worksheet #27b in the QAPP workbook.

Figure 34. Project Assessment Table

Assessment Type	Frequency	Internal or External	Organization Performing Assessment	Person(s) Responsible for Performing Assessment, Title and Organizational Affiliation	Person(s) Responsible for Responding to Assessment Findings, Title and Organizational Affiliation	Person(s) Responsible for Identifying and Implementing Corrective Actions (CA), Title and Organizational Affiliation	Person(s) Responsible for Monitoring Effectiveness of CA, Title and Organizational Affiliation

Many different types of assessments are used for evaluating the effectiveness of project activities. The following may be performed as internal or external assessments by project participants or as oversight audits by the approval authority.

Field Sampling Technical Systems Audit (TSA) – A thorough on-site audit during which sampling design, equipment, instrumentation, supplies, personnel, training, sampling procedures, chain-of-custody, sample handling and tracking, data reporting, data handling and management, data tracking and control, and data verification procedures are examined for conformance with the QAPP. It is recommended that at least one field sampling TSA be performed at the start of field sampling activities so that effective corrective action measures can be implemented to mitigate the extent and impact of identified nonconformances.

Field Analytical TSA – A thorough audit of on-site field analytical techniques (not performed in a mobile field laboratory) during which the equipment, instrumentation, supplies, personnel, training, analytical methods/procedures, sample handling and tracking, data reporting, data handling and management, data tracking and control, and data verification procedures are checked for conformance with the QAPP. A field analytical TSA can be performed prior to the start of, at the

start of, or at any time during field sampling activities. However, it is recommended that at least one field analytical TSA be performed prior to the start of the field sampling activities so that effective corrective action measures can be implemented to mitigate the extent and impact of identified nonconformances.

Field Laboratory TSA – A thorough audit of an on-site field laboratory during which the facility (e.g., mobile lab, trailer, etc.), equipment, instrumentation, supplies, personnel, training, analytical methods/procedures, laboratory procedures, sample handling and tracking, data reporting, data handling and management, data tracking and control, and data verification procedures are checked for conformance with the QAPP. A field laboratory TSA can be performed prior to the start of, at the start of, or at any time during field sampling activities. However, it is recommended that at least one field laboratory TSA be performed prior to the start of the field sampling activities so that effective corrective action measures can be implemented to mitigate the extent and impact of identified nonconformances.

Fixed Laboratory TSA – A thorough audit of a fixed laboratory during which the facility, equipment, instrumentation, supplies, personnel, training, analytical methods/procedures, laboratory procedures, sample handling and tracking, data reporting, data handling and management, data tracking and control, and data verification procedures are checked for conformance with the QAPP. A fixed laboratory TSA can be performed prior to the start of, at the start of, or at any time during field sampling activities. However, it is recommended that at least one fixed laboratory TSA be performed prior to the start of the field sampling activities so that effective corrective action measures can be implemented to mitigate the extent and impact of identified nonconformances.

Split Sampling and Analysis Audit – A comparison study to assess interlaboratory precision and accuracy. Split samples are collected by the investigative organization. The sampler collects one field sample and then physically splits it into two representative sample aliquots. One split sample is analyzed by the audit laboratory and the other by the investigative organization. Split samples quantitatively assess the measurement error introduced by the organization's sample shipment and analysis system. Split sample comparability criteria must be generated prior to sample collection and documented in an approved QAPP. Refer to Figure 12 (Section 2.7.2), Example: Data Comparison Flow Diagram and Criteria for Individual Aqueous Split Sample Results.

Performance Evaluation Sample Tracking and Analysis – Results from performance evaluation samples (PESs) are statistically analyzed to provide information on routine laboratory performance and the overall accuracy and bias of the analytical method. The QAPP must address the selection of appropriate PESs. Factors to consider include, but are not limited to, whether they are single or double blind, analyte selection, native or synthetic matrix, spiked or natively contaminated or both, multiple matrices and concentrations, total number of PESs, and analytical methods.

Data Validation TSA – A thorough review of the complete Data Validation Report, including a review of the associated analytical data package deliverables (tabulated and raw data) to ensure that all required analytical data package deliverables and Data Validation Report components were provided and contain the specified information. The Data Validation TSA also ensures that the data validation criteria specified in the QAPP were met, and the method- and laboratory-specific QC acceptance criteria specified in the QAPP were met and were appropriate for achieving the project measurement performance criteria. The Data Validation TSA also evaluates whether the project-specific measurement performance criteria and data validation criteria were appropriate for meeting the specified DQOs and whether analytical measurement performance usability issues affected DQO achievement.

Data Package TSA – This is a type of Data Validation TSA that is limited to a review of the complete analytical data package deliverable generated by the field and/or fixed laboratory or organization to ensure that all required deliverables (tabulated and raw data) are provided and contain all the information required to reproduce all reported results. The Data Package TSA also ensures that the data verification procedures specified in the QAPP were used by the laboratory/organization producing the analytical data package deliverable. The Data Package TSA ensures that the method- and laboratory-specific QC acceptance criteria specified in the QAPP were met and were appropriate for achieving the project measurement performance criteria.

Management Systems Review (MSR) – A review of an organization or organizational subset to determine if the management structure, policies, and procedures are sufficient to ensure that an effective quality system is in place to support the generation of usable project data.

Project-specific questionnaires and audit checklists are used when performing assessments. Completed checklists should be attached to the QA Management Reports as described in Section 4.2. Include project-specific audit checklists as attachments to the QAPP.

(Note: Written oversight reports and split sampling results, and subsequent corrective action responses generated by the investigative organization, should be included in QA Management Reports and final project reports.)

4.1.2 Assessment Findings and Corrective Action Responses

In this section of the QAPP, describe how QAPP deviations and project deficiencies, which are identified through the planned project assessments, will be handled. Assessment findings that require corrective action initiate a sequence of events that include documentation of deficiencies, notification of findings, request for corrective action, implementation of corrective action, and follow-up assessment of the corrective action's effectiveness.

For each type of assessment:

- Describe how deficiencies will be documented and communicated (e.g., verbal debriefing after audit and/or written audit report).
- Describe what type of corrective action responses will be required and how corrective action responses will be documented.
- Identify who will be notified of audit findings. Provide the name, title, organizational affiliation, position, and telephone/fax number of all individuals who must be notified of deficiencies/nonconformances.
- Identify to whom the corrective action responses will be directed and in what timeframe.
- Include timeframes allowed for the notification of audit findings, the request for corrective action, and the transmittal of corrective action responses.

The required information may be presented in tabular format.

The content and format of corrective action responses should be tailored to suit the project quality objectives. In certain situations, a letter documenting specific procedural changes may be a sufficient corrective action response. Appropriate procedural changes can include, but are not limited to, additional staff training, revision of SOPs, and rescheduling of field and analytical activities (e.g., to ensure holding times are met). Corrective actions that require immediate implementation to ensure that project quality objectives are met may require work to cease until those corrective actions are implemented and their effectiveness verified.

4.1.3 Additional QAPP Nonconformances

Corrective action procedures also must be implemented when deviations from the QAPP are noted by project personnel outside of the formal assessment process. In other words, corrective action needs to be initiated whenever project personnel identify field sampling and/or analytical problems that could potentially affect data quality and/or usability. Such incidents should be documented and resolved using the procedures and personnel for planned assessments that will have been described in Sections 4.1.1 and 4.1.2 of the QAPP.

4.2 QA Management Reports

Periodic QA Management Reports ensure that management and stakeholders are updated on the project status and the results of all QA assessments. Efficient communication of project status and problems allows management to implement timely and effective corrective actions so that project quality objectives can be met.

Provide a QA Management Reports table that contains the information shown in Figure 35. Identify the frequency and types of reports planned, the projected delivery dates, the personnel responsible for report preparation, and the report recipients. Figure 35 corresponds to Optional Worksheet #28 in the QAPP workbook.

Figure 35. QA Management Reports Table

Type of Report	Frequency (daily, weekly monthly, quarterly, annually, etc.)	Projected Delivery Date(s)	Person(s) Responsible for Report Preparation, Title, and Organizational Affiliation	Report Recipient(s), Title, and Organizational Affiliation

Describe the content of each of the QA Management Reports that will be generated for the project (those listed in the table). Assessment checklists and reports, and requests for corrective actions letters (refer to Section 4.1), should be included as attachments to the QA Management Reports. Also, copies of all corrective action response letters should be included as attachments to the QA Management Reports. QA Management Reports should include an evaluation of measurement error as determined from the assessments.

All QA Management Reports must be included in the Final Project Report. If no QA Management Reports are generated for the project, then a QA/QC section that discusses the following issues must be included in the Final Project Report:

- Summary of project QA/QC programs and trainings conducted during the project
- Conformance of project activities to QAPP requirements/procedures
- Status of project and schedule delays
- Deviations from the approved QAPP and approved amendments to the QAPP
- Results and trends of PESs by laboratory (per parameter, matrix, and concentration level)
- Description and findings of TSAs and other assessments
- Results of data validation activities in terms of amount of usable data generated
- Required corrective actions and effectiveness of corrective action implementation
- Data quality assessments in terms of precision, accuracy, representativeness, completeness, comparability, and sensitivity (refer to Section 5.2)
- Limitations on the use of measurement data generated

The Final Project Report must meet project quality objectives and, at a minimum, include:

- Development of project quality objectives, narrative, and timeline of project activities
- Summary of major/critical problems encountered and their resolution

- Data summary including tables, charts, and graphs with appropriate sample identification/ station location numbers, concentration units, percent solids (if applicable), and data quality flags
- Reconciliation of project data with project quality objectives
- Conclusions and recommendations
- All QA Management Reports (as attachments to the Final Project Report document) and/or the QA/QC section that addresses the issues listed above

5.0 DATA VERIFICATION/VALIDATION AND USABILITY ELEMENTS

This QAPP element group encompasses the activities used to ensure that only scientifically sound data that are of known and documented quality and that meet project quality objectives are used in making environmental decisions. The data review approach must be of a level appropriate to the project requirements.

This UFP-QAPP Manual defines two distinct evaluative steps that are required to ensure that project data quality needs are met:

1. **Data Verification/Validation** – Data verification/validation consists of evaluating the completeness, correctness, and conformance or contractual compliance of a data set against the method standard, SOP, or contract requirements documented in the project QAPP. This activity should be performed internally by the analytical group or fixed laboratory generating the data. Data can be checked by an entity external to the analytical group or fixed laboratory. In addition, the qualification of data beyond method, procedure, or contract compliance is done to determine the analytical quality of a specific data set. These criteria are based on the measurement performance criteria developed in Section 2.7 of the project QAPP. This UFP-QAPP Manual states that this activity *must* be performed by an organization independent of the group that generates the data. Data verification/validation results in accepted, qualified, or rejected data.

2. **Data Usability Assessment** – The purpose of a data usability assessment is to evaluate verified/validated data to determine if they can be used for the purpose of the project, i.e., to answer the environmental question or to make the environmental decisions that must be made. Data usability assessment includes the following sequence of evaluations:

   – First, individual data sets are evaluated to identify the measurement performance/ usability issues/problems affecting the ultimate achievement of DQOs.

   – Second, an overall evaluation of *all* data generated for the project is performed.

   – Finally, the project-specific measurement performance criteria and data verification/ validation criteria documented in the QAPP are evaluated to determine if they were appropriate for meeting DQOs.

In order to perform either of the data evaluation steps above, it is necessary that reported data be supported by complete data packages (as itemized in Tables 6 and 7 of Section 3.5.1.3), which include sample receipt and tracking information, chain-of-custody records, tabulated data summary

forms and raw analytical data for all field samples, standards, QC checks and QC samples, and all other project-specific documents that are generated.

If relevant raw data and/or sample information documenting data quality are not available, then data verification/validation cannot be performed and only a limited data review can be performed. This UFP-QAPP Manual defines reviews of data/information that do not have sufficient, documented QC as "limited data reviews" (LDRs). LDRs result in unquantifiable measurement error and an unknown degree of uncertainty associated with the data. Such data are considered to be unknown and of undocumented quality. Ultimately, decisions that are made based on the data may be wrong. Data that are of unknown or undocumented quality should only be used in exceptional circumstances. Resampling or reanalysis must be considered first.

5.1 Data Verification and Validation

5.1.1 Requirements

Verification and validation procedures and criteria must be established prior to data evaluation. Specific project verification and validation criteria are developed to identify and qualify data that do not meet the measurement performance criteria as established in Section 2.7. Data verification and validation criteria and procedures are documented in this section of the QAPP to ensure that data are evaluated properly, completely, and consistently for use in meeting project quality objectives. Validation guidance and documents can be attached to the QAPP.

Specify the data validation process that will be used to verify and validate sample collection, handling, field analysis, and analytical laboratory project data. Identify the specific data validation process that will be used for each analytical parameter, matrix, and concentration level.

Document the procedures and criteria used to verify and validate data information operations. These operations include, but are not limited to, the electronic and/or manual transfer, entry, use, and reporting of data for computer models, algorithms, and databases; correlations studies between variables; data plotting and so forth.

Request to Reviewers

The IDQTF Workgroup is soliciting comments on how to handle and give direction on the issues of data verification and validation. Many entities have working definitions that make strong distinctions between these terms, while others, for practical purposes, use the terms interchangeably. What direction/instructions should be in these sections? Should verification and validation be addressed separately? What are good definitions for these terms? What procedures should be followed?

5.1.2 Procedures

This section of the QAPP describes the process that will be followed to verify and validate project data. Provide a table that contains the information shown in Figure 36. Figure 36 corresponds to Optional Worksheet #29a in the QAPP workbook.

Figure 36. Data Verification/Validation Process Table

Verification/ Validation Task	Description	Internal/ External	Responsible for Verification/Validation (Name, Organization)

Describe how sample collection, handling, and field analysis procedures will be verified/validated internally against the measurement performance criteria specified in Section 2.7. Describe how verification/validation of field sampling, handling, and analysis activities will be documented (e.g., QC signatures in field logs, QC checklist, etc.). Describe which sampling, handling, field analytical, and fixed laboratory data will be verified/validated internally at the data generator level. Describe the end product of laboratory verification (e.g., laboratory-qualified data).

Describe which handling, field analytical, and fixed laboratory data will be verified/validated by entities external to the data generator.

Describe the matrices, concentration levels, and analytical parameters for which each data verification/validation group will be responsible. It is recommended that this information be provided in a table.

Provide a data verification/validation summary table that contains the information shown in Figure 37. Identify the matrices, analytical parameters, and concentration levels that each data verification/validation group will be responsible for, as well as the verification/validation criteria that will be used to verify and validate those data. Identify by title (lead chemist, project chemist, etc.) and organizational affiliation the person who is ultimately responsible for data verification/

validation. This is the person who will sign the project Data Verification/Validation Reports. Figure 37 corresponds to Optional Worksheet #29b in the QAPP workbook.

Figure 37. Data Verification/Validation Summary Table

Medium/ Matrix	Analytical Parameter	Concentration Level	Verification/ Validation Criteria	Data Verifier/Validator (Title and organizational affiliation)	Responsibility for Data Verification/Validation (Title and organizational affiliation)

5.2 Data Usability and Reconciliation with Data Quality Objectives

This section of the QAPP describes how verified/validated project data will be reconciled with the data quality objectives, how data quality issues will be addressed, and how limitations on the use of the data will be reported and handled. The section describes the scientific and statistical procedures/ methods that will be used to determine whether data are of the right type, quality, and quantity to support environmental decision-making for the project. (Note: Data quality assessment is the final step in data evaluation and can only be performed on data of known and documented quality, that is, verified/validated data.)

Summarize the data assessment process and all data assessment procedures, including statistics, equations, and computer algorithms, that will be used to assess data. Describe the data generation reporting formats and the documentation that will be generated during data assessment. Identify the personnel (by title and organizational affiliation) responsible for performing the data usability assessment. Optional Worksheet #30 in the QAPP workbook can be used for this purpose.

A Formal Data Quality Assessment (DQA) Process is described in *Guidance for the Data Quality Assessment Process: Practical Methods for Data Analysis*, EPA QA/G-9, July 1996. EPA QA/G-9 provides guidance on many statistical and graphical assessment tools. The Formal DQA Process consists of five steps:

1. Review DQOs and sampling design
2. Conduct preliminary data review
3. Select statistical test
4. Verify assumptions
5. Draw conclusions from the data

Request to Reviewers

What specific DoD and DOE documents are equivalent guidance documents to EPA QA/G-9?

Even if the Formal DQA Process is not followed in its entirety, a systematic assessment of the data quality must be performed. This process should include a preliminary data review. It is

recommended that the QAPP include a flow diagram to describe the data quality assessment process for the project.

Describe how data will be presented in order to identify trends, relationships (correlations), and anomalies.

Describe the evaluative procedures used to assess overall measurement error associated with the project and include the following data quality indicators (DQIs).

Precision

In order to meet the needs of the data users, project data must meet the measurement performance criteria for precision specified in Section 2.7.2 of the QAPP.

Project Precision (Field Duplicates/Replicates): Include formulae for calculating precision for individual duplicate/replicate data points (e.g., RPD, RSD, standard deviation (SD)).

Analytical Precision (Laboratory Duplicates/Replicates, etc.): Include the formulae for calculating analytical precision for individual duplicate/replicate data points (e.g., RPD, RSD, SD).

Overall Precision: Describe the procedures used to perform overall assessment of precision in terms of the entire set of project data and include mathematical and/or statistical formulae for evaluating overall precision.

Poor overall precision may be the result of one or more of the following: field instrument variation, analytical measurement variation, poor sampling technique, sample transport problems, and/or spatial variation (heterogeneous sample matrices). In order to identify the cause of imprecision, the field sampling design rationale and sampling techniques should be evaluated by the reviewer, and both field and analytical duplicate/replicate sample results should be reviewed. If poor precision is indicated in both the field and analytical duplicates/replicates, then the laboratory may be the source of error. If poor precision is limited to the field duplicate/replicate results, then the sampling technique, field instrument variation, sample transport, and/or spatial variability may be the source of error.

If Data Validation Reports indicate that analytical imprecision exists for a particular data set or sample delivery group (SDG), then the impact of that imprecision on data usability must be discussed in the Data Assessment Report.

The Data Assessment Report should discuss and compare overall field duplicate precision data from multiple data sets collected for the project for each matrix, analytical parameter, and concentration

level. Data Assessment Reports should describe the limitations on the use of project data when overall precision is poor or when poor precision is limited to a specific sampling or laboratory/analytical group, data set/SDG, matrix, analytical parameter, or concentration level.

When project-required precision is not achieved and project data are not usable to adequately address environmental questions (i.e., determining if regulatory/technical Action Limits have been exceeded) and to support project decision-making, then the Data Assessment Report should address how this problem will be resolved and discuss the potential need for resampling.

Accuracy/Bias

In order to meet the needs of the data users, project data must meet the measurement performance criteria for accuracy/bias specified in Section 2.7.2 of the QAPP.

Sample Contamination: Discuss how the QC activities and QC check and sample data will be reviewed to evaluate the accuracy and potential bias of sample results. If field contamination exists, then the impact of field contamination on data usability must be discussed in the Data Assessment Report, and the field sampling team leader and Project Manager should be notified. Differentiate field sample collection and transport contamination (equipment/rinsate blanks, trip blanks) from contamination introduced at the time of sample preparation and/or analysis (i.e., method blank, storage blank, analytical instrument blanks). Note that sample contamination may result in either a negative or positive bias. For example, improperly cleaned sample containers for metal analysis may result in the retention of metals on the interior container walls. This would result in lower metals concentrations being reported than are actually present in the collected sample (i.e., a negative bias). A positive bias would occur when sample container contamination results in an additive effect, i.e., reported analyte concentrations are higher than the true sample concentrations for that analyte.

Analytical Accuracy/Bias: Discuss how the QC activities and QC check and sample data will be used to evaluate the accuracy and potential bias of sample results. Include methods/formulae for calculating analytical accuracy and bias for spike samples/compounds (matrix spikes, surrogate spikes, SRMs, LCSs, etc.), PESs, calibration linearity, results of calibration verification checks, etc. If Data Validation Reports indicate that contamination and/or analytical inaccuracies/bias exist for a particular data set/SDG, then the impact of that contamination and/or analytical inaccuracy/bias on data usability must be discussed in the Data Assessment Report.

Overall Accuracy/Bias: Describe the procedures used to perform overall assessment of accuracy/bias in terms of the entire set of project data and include mathematical and/or statistical formulae for evaluating overall accuracy/bias. Describe the procedures for evaluating the overall qualitative and quantitative bias trends in PES data.

The Data Assessment Report should discuss and compare overall contamination and accuracy/bias data from multiple data sets collected for the project for each matrix, analytical parameter, and concentration level. The Data Assessment Report should describe the limitations on the use of project data if extensive contamination and/or inaccuracy/bias exists or when it is limited to a specific sampling or laboratory/analytical group, data set/SDG, matrix, analytical parameter, or concentration level. The Data Assessment Report should identify qualitative and/or quantitative bias trends in multiple PES results for each matrix, analytical parameter, and concentration level. The impact of any qualitative and/or quantitative trends in bias on the sample data should be discussed. **Any PESs that have false positive and/or false negative results should be reported and the impact on data usability should be discussed in the Data Assessment Report.**

When project-required accuracy/bias is not achieved and project data are not usable to adequately address environmental questions (i.e., determining if regulatory/technical Action Limits have been exceeded) and to support project decision-making, then the Data Assessment Report should address how this problem will be resolved and discuss the potential need for resampling.

Sample Representativeness

In order to meet the needs of the data users, project data must meet the measurement performance criteria for sample representativeness specified in Section 2.7.2 of the QAPP.

Discuss how the QA/QC activities (review of sampling SOPs, field sampling TSAs, split sampling and analysis audits, etc.) and QC check and sample data will be reviewed to assess sample representativeness. If field duplicate precision checks indicate potential spatial variability, then this may trigger additional scoping meetings and subsequent resampling in order to collect data that are more representative of a nonhomogeneous site.

The Data Assessment Report should discuss and compare overall sample representativeness for each matrix, parameter, and concentration level. Data Assessment Reports should describe the limitations on the use of project data when overall nonrepresentative sampling has occurred or when nonrepresentative sampling is limited to a specific sampling group, data set/SDG, matrix, analytical parameter, or concentration level. If data are not usable to adequately address environmental questions and/or support project decision-making, then the Data Assessment Report should address how this problem will be resolved and discuss the potential need for resampling.

Comparability

In order to meet the needs of the data users, project data must meet the measurement performance criteria for comparability specified in Section 2.7.2 of the QAPP.

Include methods/formulae for assessing data comparability for each matrix, analytical parameter, and concentration level.

If two or more sampling procedures and/or sampling teams will be used to collect samples, describe how comparability will be assessed for each matrix, analytical parameter, and concentration level.

If two or more analytical methods/SOPs will be used to analyze samples of the same matrix and concentration level for the same analytical parameter, describe how comparability will be assessed between the two data sets.

If field screening data will be confirmed by full-protocol methods, document the specific method references and percent difference formula that will be used to assess comparability for individual data points (refer to Section 2.7.2). To document overall comparability, describe the procedures used to perform overall assessment of comparability and include mathematical and/or statistical formulae for evaluating screening and confirmatory data comparability.

If split samples are analyzed for EPA oversight, document the specific method references and percent difference formula that will be used to assess split sample comparability for individual data points (refer to Section 2.7.2). To document overall comparability, describe the procedures used to perform overall assessment of oversight split sampling comparability and include mathematical and/or statistical formulae for evaluating oversight split sampling data comparability.

For long-term monitoring projects, data comparability is extremely important. Project data should be compared to previously generated data to ascertain the possibility of false positives and/or false negatives and negative and/or positive trends in bias. Anomalies detected in the data may reflect a changing environment or indicate sampling and/or analytical error. Comparability criteria should be established to evaluate these data sets in order to identify outliers and trigger resampling as warranted.

The Data Assessment Report should discuss and compare overall comparability between multiple data sets collected for the project for each matrix, analytical parameter, and concentration level. The Data Assessment Report should describe the limitations on the use of project data when project-required data comparability is not achieved for the overall project or when it is limited to a specific sampling or laboratory/analytical group, data set/SDG, matrix, analytical parameter, or concentration level.

If screen/confirmatory comparability criteria are not met, then this should be documented in the Data Assessment Report and the impact on data usability should be discussed therein. Likewise, if oversight split sampling comparability criteria are not met, then the Data Assessment Report should document this and discuss the impact on data usability. If data are not usable to adequately address

environmental questions and/or support project decision-making, then the Data Assessment Report should address how this problem will be resolved and discuss the potential need for resampling.

Finally, if long-term monitoring data are not comparable, then the Data Assessment Report should address whether the data indicate a changing environment or are a result of sampling and/or analytical error. If data are not usable to adequately address environmental questions and/or support project decision-making, then the Data Assessment Report should address how this problem will be resolved and discuss the potential need for resampling.

Sensitivity and Quantitation Limits

In order to meet the needs of the data users, project data must meet the measurement performance criteria for sensitivity and QLs specified in Section 2.7.2 of the QAPP.

Include methods/formulae for calculating analytical sensitivity that ensure QLs are achieved (e.g., percent recovery of laboratory-fortified blank spiked compounds and PESs). Also, include procedures for evaluating low point calibration standards run at the QL. Low point calibration standards should produce a signal at least 10 times the background noise level and should be part of a linear calibration curve.

Document the procedures for calculating MDLs, QLs, and SQLs.

Overall Sensitivity and Quantitation Limits: Describe the procedures used to perform overall assessment of sensitivity and QLs in terms of the entire set of project data, and include mathematical and/or statistical formulae for evaluating sensitivity and QLs.

If Data Validation Reports indicate that sensitivity and/or QLs were not achieved, then the impact of that lack of sensitivity and/or higher QLs on data usability must be discussed in the Data Assessment Report.

The Data Assessment Report should discuss and compare overall sensitivity and QLs from multiple data sets collected for the project for each matrix, analytical parameter, and concentration level. Data Assessment Reports should describe the limitations on the use of project data if project-required sensitivity and QLs were not achieved for all project data or when it is limited to a specific sampling or laboratory/analytical group, data set/SDG, matrix, analytical parameter, or concentration level.

When project-required QLs are not achieved and project data are not usable to adequately address environmental questions (i.e., determining if regulatory/technical Action Limits have been exceeded) and to support project decision-making, then the Data Assessment Report should address how this

problem will be resolved and discuss the potential need for resampling. In this case, the Data Assessment Report should clearly differentiate between usable and unusable data for the data users.

Data Limitations and Actions

Describe what actions will be taken when data do not meet the project quality objectives. It is necessary to document, in this section of the QAPP, the exact process for handling data that do not meet project quality objectives (i.e., when DQIs do not meet measurement performance criteria). Depending on how those data will be used, the process should specify the restrictions on use of those data for environmental decision-making.

Sources of sampling and analytical error should be identified and corrected as close as possible to the onset of sample collection activities. Incorporating an ongoing data assessment process throughout the project, rather than just as a final step, will facilitate the early detection and correction of problems, thereby ensuring that project quality objectives are met.

Completeness

In order to meet the needs of the data users, project data must meet the measurement performance criteria for data completeness specified in Section 2.7.2 of the QAPP.

Include the methods/formulae for calculating data completeness. Describe how the amount of valid data will be determined as a percentage of the number of valid measurements that should have been collected for each matrix, analytical parameter, and concentration level. When certain sample locations and/or analytes and matrices are more critical than others in making project decisions, describe how critical data will be assessed for completeness.

Overall Completeness: Describe the procedures used to perform overall assessment of completeness in terms of the entire set of project data and include mathematical and/or statistical formulae for evaluating overall completeness.

The Data Assessment Report should discuss and compare overall completeness of multiple data sets collected for the project for each matrix, analytical parameter, and concentration level. Data Assessment Reports should describe the limitations on the use of project data if project-required completeness was not achieved for the overall project or when it is limited to a specific sampling or laboratory/analytical group, data set/SDG, matrix, analytical parameter, or concentration level.

When project-required completeness is not achieved and sufficient data are not available to adequately address environmental questions and support project decision-making, then the Data Assessment Report should address how this problem will be resolved and discuss the potential need for additional resampling.

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Intergovernmental Data Quality Task Force, Uniform Federal Policy for Implementing Environmental Quality Systems: Evaluating, Assessing and Documenting Environmental Data Collection/Use and Technology Programs, Interim Final, Version 1, November 2000.

APPENDIX A

QUESTIONS AND ANSWERS REGARDING THE *DRAFT UNIFORM FEDERAL POLICY FOR QUALITY ASSURANCE PROJECT PLANS*

QUESTIONS AND ANSWERS REGARDING THE *DRAFT UNIFORM FEDERAL POLICY FOR QUALITY ASSURANCE PROJECT PLANS (UFP-QAPP MANUAL)*

I. Background

Q.1 What is a Quality Assurance Project Plan (QAPP)?

A.1 ANSI/ASQC E4 Part B requires that a QAPP be approved for all data collection projects. A QAPP will integrate technical and quality control aspects of a project throughout its life cycle, including planning, implementation, assessment, and corrective actions. A QAPP is a document that presents the steps that will be taken to ensure that environmental data collected are of the correct type and quality required for a specific decision or use. It presents an organized and systematic description of the ways in which quality assurance (QA) and quality control (QC) will be applied to the collection and use of environmental data.

Q.2 What is the purpose of the *Draft UFP-QAPP Manual* that is being produced by the Intergovernmental Data Quality Task Force (IDQTF)?

A.2 The purpose is to produce a single national consensus guidance document that implements the requirements of ANSI/ASQC E4 Part B consistently and systematically across the Federal agencies involved in the IDQTF (currently EPA, DoD, and DOE).

Q.3 Why do Federal agencies need another QAPP guidance document?

A.3 Many Federal agencies have independently created their own QAPP guidance. EPA has two QAPP guidance documents that encompass all the elements of a Systematic Planning that should be addressed in a QAPP. These two documents are **QA/R5, *EPA Requirements for Quality Assurance Project Plans***, and **QA/G5, *EPA Guidance for Quality Assurance Project Plans***. DoD and DOE have independently developed their own approach to QAPP guidance. Different programs or components of these agencies may also have their own QAPP guidance. In some cases, the agency's QAPP guidance may not address all of the elements that EPA considers to be important in a QAPP. For example, the Air Force Center for Environmental Excellence (AFCEE) QAPP guidance primarily addresses laboratory data quality. AFCEE addresses other elements of EPA's QAPP guidance, such as sampling and analysis plans and systematic planning, in separate AFCEE guidance documents (e.g., guidance on work plans and sampling plans).

In addition, although EPA has Agency-wide QAPP guidance, many EPA Regions have independently developed their own implementation tools, including supplemental QAPP guidance or "model QAPPs," with one Region's tools differing from another Region's.

The different types of QAPP guidance and associated implementation tools often result in uncertainty as to what is expected, conflict between agencies, and rework. Different reviewers and preparers of QAPPs have different expectations of what should be in a QAPP.

An approach to a QAPP that is deemed suitable for one Region may not be suitable in another Region. A DoD component may create a QAPP that has some, but not all, of the parts EPA considers important.

Because approaches and requirements for QAPPs differ among Federal agencies, the IDQTF believes it is necessary to implement a QAPP guidance that is applicable to any Federal agency. The *Draft UFP-QAPP Manual*, developed by the IDQTF to provide a common organizational framework and approach to QAPPs, will reduce conflict and provide all who are involved at Federal facilities with a common set of guidelines and expectations. The IDQTF provides all agencies with an opportunity to participate in developing a coordinated intergovernmental program to improve data quality.

II. Basis for the IDQTF *Draft UFP-QAPP Manual*

Q.4 What is the basis for the Consensus QAPP Guidance?

A.4 The IDQTF agreed to use ANSI/ASQC E4 Part B requirements as the basis for QAPP guidance. Although ANSI/ASQC E4 Part B established standards describing the essential elements of a QAPP, it lacks sufficient detail to promote the degree of consistency needed to address the issues of common expectations, conflict, and rework. A recently developed Region 1 (New England) QAPP guidance was the point of departure for creation of the *Draft UFP-QAPP Manual*.

Q.5 Why was the Region 1 QAPP guidance document selected as the base document for a national consensus QAPP guidance document?

A.5 The Region 1 QAPP guidance document was selected by the IDQTF as the base document for the *Draft UFP-QAPP Manual* because of its breadth of coverage, level of detail, and structured implementation tools. Specifically, the Region 1 QAPP guidance has three elements that the IDQTF believed would be helpful in ensuring the development of consistent and thorough QAPP documents:

- It encompasses the entire EPA Systematic Planning Process and, if followed, will ensure that the project team goes through the planning process together.
- It includes extensive definitions, explanatory material, and examples.
- It has a series of tables that can be filled in and a minimum of text, which assist in creating a short, easy-to-follow QAPP.

The IDQTF believes that the level of specificity in the Region 1 guidance document, as well as its extensive implementation tools, helps to minimize inconsistencies among QAPPs and makes them easier (and therefore quicker and cheaper) to review. In addition, although the resulting guidance document is itself lengthy, the use of an easy-to-use tabular format is likely to reduce the length of submitted QAPPs by eliminating the need for superfluous and repetitive verbiage. Finally, the Region 1 QAPP was extensively reviewed by a subgroup of

the IDQTF and modified to make its use appropriate across all Federal agencies, including all of the EPA Regions.

Q.6 Why wasn't *EPA Requirements for Quality Assurance Project Plans* (EPA QA/R-5) or *EPA Guidance on Quality Assurance Project Plans* (QA/G-5) used as the base document?

A.6 Although the *Draft UFP-QAPP Manual* is consistent with both EPA QA/R-5 and QA/G-5, it provides a greater level of detail and more implementation tools than do either of those documents. In addition, QA/R-5 applies specifically to EPA-funded projects and is too EPA-specific in terms of language and process, according to the IDQTF. QA/G-5 is a broad guidance document and lacks the specificity and the implementation tools that the IDQTF believes will make the draft Federal consensus document so useful. Finally, the *Draft UFP-QAPP Manual* is consistent with QA/R-5, QA/G-5, and the QAPP requirements outlined in Chapter 5 of the EPA Quality Order 5360.1 A2.

Q.7 Doesn't the use of the Contract Laboratory Program (CLP) provide sufficient quality assurance for environmental data by "ensuring data of known and documented quality"?

A.7 No. The CLP provides a series of contract specifications, in the form of a statement of work (SOW), that covers laboratory services purchased under specific contracts for Superfund sites. The CLP also provides guidelines for evaluating laboratory conformance to its contract specifications; however, it does not address any of the data usability requirements and therefore does not provide assurance that collected data are appropriate for their intended uses. There are many environmental programs that are not covered by CLP, and many aspects of environmental data collection and environmental technology programs are outside its scope (e.g., the Systematic Planning Process, sampling activities, QA oversight). The CLP does not address overall Quality Systems.

III. Implementation Issues

Q.8 How will this *Draft UFP-QAPP Manual* be used and implemented?

A.8 Each participating Federal agency will develop its own implementation plans that recognize the contracts through which the UFP-QAPP Manual will be implemented, the status of previously approved QAPPs, and the stage of the data collection effort. It is anticipated that the Consensus QAPP Guidance will be used to develop future QAPPs for the managing the collection and use of environmental data at Federal facilities.

Q.9 What if I already have an approved QAPP? Will I have to totally rewrite it to comply with the *Draft UFP-QAPP Manual*?

A.9 No. If you have an approved QAPP, there is no reason to redo it. The QAPP guidance is aimed at future data collection efforts. Approved project-specific QAPPs will remain acceptable for ongoing data collection activities until the projects are complete.

It should be noted that the Consensus QAPP Guidance suggests that all QAPPs undergo an annual review to verify that the QAPP is still up-to-date. It also requires that all QAPPs be reviewed and, if necessary, rewritten every 5 years. This would apply to generic or facility-wide QAPPs as well as to site-specific QAPPs.

Q.10 What if I have an approved generic basewide or facilitywide QAPP?

A.10 Generic or facility-wide QAPPs are written to address elements of data collection that generally don't change from site to site. They are always supplemented by site-specific QAPPs, standard operating procedures (SOPs), Sampling and Analysis Plans (SAPs), and Field Sampling and Analysis Plans (FSAPs) that address issues that cannot be addressed by the generic or facility-wide QAPP. The consensus guidance specifically allows cross-referencing to other documents that contain relevant information. Approved generic or facility-wide QAPPs should not be discarded, but rather should be referenced in appropriate parts of the site-specific QAPP to help create a more focused document.

Q.11 Does the *Draft UFP-QAPP Manual* replace existing guidance documents?

A.11 The consensus QAPP guidance is consistent with existing guidance documents. When adopted by EPA, it will replace existing Regional guidance and Regional model QAPPs. It will not replace EPA QA/R-5 or EPA QA/G-5, as it is consistent with, but does not duplicate, those documents. The **Consensus QAPP Guidance** is an implementation guide that, if used properly, should simplify both the development and review of QAPPs. When adopted by participating Federal agencies (e.g. EPA, DoD, DOE), it is anticipated that new QAPPs will be consistent with the consensus guidance.

Q.12 What are the steps involved in refining and issuing as the *Draft UFP-QAPP Manual* as a final document?

A.12 While the Consensus QAPP Guidance is being reviewed, the IDQTF will conduct beta-testing of the document on a variety of projects. The beta-testing will serve the dual purposes of obtaining examples of a graded approach to QAPP preparation and assessing the usability of the QAPP guidance for smaller projects. These additional examples and any other modifications that result from the beta-testing will be incorporated into the next version of the document along with changes that are identified in the review and comment process.

An interim final draft of the QAPP guidance will be developed based on the comments obtained in this initial review and the results of the beta-testing. It will be issued for agency and stakeholder review in 2001. The final guidance document should be ready for agencies to issue in late 2001.

QAPP Guidance Development Activity	Projected Time Frame
Issue document for agency review	November 2000
Conduct beta-testing	November 2000-February 2001
Review document (Agencies)	November 2000-February 2001
Review agency comments (IDQTF)	February-April 2001
Revise document	April-May 2001
Review interim final draft (Stakeholders and agencies)	May 2001-August 2001
Review stakeholder and agency comments (IDQTF)	September 2001-October 2001
Revise document	October 2001
Issue final guidance document	November 2001

Q.13 How will the *Draft UFP-QAPP Manual* be implemented and what is the timeframe for implementation?

A.13 The development of the *Draft UFP-QAPP Manual* was the result of two intergovernmental Memoranda of Understanding (MOU). One was between the EPA and DoD and the second was between EPA and DOE. Implementation will be the subject of future MOUs.

The *Draft UFP-QAPP Manual* is expected to improve the quality of QAPPs, streamline their development, and provide significantly greater consistency of QAPP content for work conducted for Federal facilities. This is expected to reduce the number of disagreements between Federal facilities and EPA across all 10 EPA Regions. Since the vast majority of these QAPPs will be generated by contractors, implementation of the QAPP guidance will be, at least in part, through contracts. Since DoD components and DOE offices each have unique contracting practices, each agency will need to determine its strategy and timeframe for implementation. Implementation could be conducted in phases as existing contracts expire and new ones are implemented.

Q.14 If the *Draft UFP-QAPP Manual* is the required guidance document for developing QAPPs, what happens if an agency fails to follow it? Will noncompliance result in a notice of violation?

A.14 Failure to implement the UFP-QAPP Manual will not result in a notice of violation. The *Draft UFP-QAPP Manual* will be implemented voluntarily by parties to the second intergovernmental MOU. Since the Consensus QAPP guidance was not developed or promulgated through the Federal rule-making process, it does not have the force of regulation and is not subject to regulatory enforcement or a notice of violation. The purpose of the Consensus QAPP Guidance is to assist project teams in creating consistent, high-quality, and easy to review documents. Each agency must develop its own procedures for assessing

nonconformance and initiating appropriate corrective action. Only in circumstances in which two parties choose to make use of the UFP-QAPP Manual part of an enforceable agreement (e.g., such as a Federal Facilities Agreement) could failure to use it potentially result in a notice of violation. In general, the consequences of not using the UFP-QAPP Manual will be continuation of the conflicts and rework that currently permeate the data collection and review process.